Exhibit 4

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK

Expert Report of Timothy E. Kosty

January 12, 2022

TABLE OF CONTENTS

TABLE OF ABBREVIATIONS

Acronym	Meaning
AACG	Advanced Analytical Consulting Group, Inc.
ACA	Affordable Care Act
ACE-I	Angiotensin-converting enzyme inhibitor
AHP	A trade or business association health plan
AMCP	Academy of Managed Care Pharmacy
ANDA	Abbreviated New Drug Application
API	Active pharmaceutical ingredient
ARB	Angiotensin II receptor blocker
ARNI	Angiotensin-receptor neprilysin inhibitor
ASO	Administrative services only
AWP	Average Wholesale Price
BIN	Bank Identification Number (replaced by NCPDP issued IID)
BLA	Biologics Licensing Arrangement
CMS	Centers for Medicare & Medicaid Services
DIR fees	Direct and indirect remuneration fees
DOL	U.S. Department of Labor
DSCSA	Drug Supply Chain Security Act
EGWP	Employer Group Waiver Programs
EPO	Exclusive Provider Organization
ERISA	Employee Retirement Income Security Act of 1974
ESI	Express Scripts
FDA	U.S. Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FFS	Fee-for-service
GER	Generic effective rate
GPO	Group purchasing organization
GRP	Group ID (Payor issued)
HCTZ	Hydrochlorothiazide
HIX	ACA Healthcare Exchange
HMO	Health Maintenance Organization
IID	Issuer Identification Number (NCPDP issued; replaces BIN)
LIS	Low-income subsidy
MAC	Maximum allowable cost
MADA	Maine Automobile Dealers Association
MAO	Medicare Advantage Organization
MA-PD	Medicare Advantage Prescription Drug Plan
MCO	Managed care organization
MEHP	Multi-employer health plan
MOOP	Maximum out of pocket
MSP	MSP Recovery Claims, Series LLC
NCPDP	National Council for Prescription Drug Programs
NCSL	National Conference of State Legislatures

Acronym	Meaning
NDA	New Drug Application
NDC	National Drug Code
NDEA	N-Nitrosodiethylamine
NDMA	N-Nitrosodimethylamine
NMBA	N-Nitroso-N-methyl-4-aminobutyric acid
PBMI	Pharmacy Benefit Management Institute
PCN	Processor control number (payor issued)
PDP	Prescription Drug Plan
PHSI	Pharmacy Healthcare Solutions, Inc.
PHSL	Pharmacy Healthcare Solutions, LLC
PBM	Pharmacy benefit manager
PPO	Preferred provider organization
PSAO	Pharmacy service administrative organization
P&T committees	Pharmacy and therapeutics committees
RDS	Medicare Part D - Employer Retiree Drug Subsidy
RFP	Request for proposal
SPBA	Society of Professional Benefit Administration
TDI	TDI Managed Care Services, Inc.
TPA	Third-party administrator
TPP	Third Party Payor
VAC	Value Assessment Committee
VCD	Valsartan-containing drug
ZHP	Zhejiang Huahai Pharmaceutical Co.

I. Overview

A. Qualifications

1. As set forth in my attached curriculum vitae ("CV"), I graduated from the Ohio State University with a Bachelor of Science degree in Pharmacy in 1983. In 1993, I earned a Master of Business Administration from Pennsylvania State University. I have worked in pharmacy- related businesses for more than 38 years and have written extensively on topics related to the pharmacy industry.

2. I co-founded Pharmacy Healthcare Solutions, Inc. ("PHSI") in 1996. PHSI provides management consulting services in the pharmacy industry working with many market segments, including pharmaceutical manufacturers, health plans, pharmacy benefit managers ("PBMs"), discount card programs, retail, mail, and specialty pharmacies, and technology companies that support their business needs. My area of focus is on the business of pharmacy. I am actively involved in client projects in all segments of the pharmacy industry. I am primarily responsible for the management oversight of PHSI. In 2018, I co-founded Pharmacy Healthcare Solutions, LLC ("PHSL"). PHSL was created to facilitate the transfer of ownership of PHSI to a new ownership group. The services PHSL offers are not materially different from the services PHSI offered.

3. Before founding PHSI, I helped create the PBM known as TDI Managed Care Services, Inc. ("TDI") in 1993 and managed its administrative functions until 1996. I was responsible for creating the operational functions of the company. My responsibilities included creating and negotiating a nationwide network of retail pharmacies; creating a customer service function to respond to client, member, and pharmacy telephone inquiries; and leading the functional evaluation, selection, and installation of RxClaim, a multimillion-dollar claims processing system to handle online real-time claims adjudication. RxClaim was one of the first pharmacy claims processing systems available in the market offered by ComCoTec. This system is still in use today as the asset was rolled up through acquisitions and is owned by OptumRx today, which was acquired as part of OptumRx's Catamaran acquisition. I was also responsible for information systems development projects to enhance TDI's product offering.

4. Before TDI, I worked in retail pharmacy operations for Thrift Drug, Inc. between 1992 and 1993, and Rite Aid Corporation from 1983 to 1992. My work at Thrift Drug and Rite Aid included, among other things, a focus on third-party administration, pharmacy dispensing software, prescription pricing, and pharmacy profitability issues involving, among other things, issues related to third-party reimbursement and the cost of goods.

5. As a result of my more than 38 years in the pharmacy business—13 years working at retail chain pharmacies and PBMs and 25 years working as a consultant—I have considerable expertise assisting PHSI clients manage and implement pharmacy benefit programs on behalf of PBM and self-insured clients. This assistance has included managing the request for proposal ("RFP") process, evaluating PBM bids from both qualitative and quantitative perspectives, and assisting clients in the process of negotiating the material terms and conditions of particular concern to the client in their PBM agreements. I have assisted PBMs, Medicare Part D plans, and Medicaid fiscal intermediaries negotiate rebate agreements with pharmaceutical manufacturers. I have participated in pharmacy and therapeutics ("P&T") committees as an *ex officio* member (non-voting) and understand the inner workings of P&T committees.

6. Additionally, PHSI has provided due diligence services to its clients that are looking to acquire PBMs as part of their growth strategy. PHSI has assisted PBMs in over a dozen due diligence projects and in understanding the financial drivers of the PBM business model. This review includes a financial synergies analysis using pharmacy claims data obtained from both parties to evaluate a combined entities pharmacy network contracts and pharmaceutical manufacturer rebate agreements. I have also evaluated claims processing systems to assist in determining the go-forward strategy to identify a successor claims processing system that could be used by both parties.

7. Individually and as part of PHSI, I am a member of a number of industry organizations. For more than 20 years, I have been a member of the National Council for Prescription Drug Programs and participated in the development process for Telecommunications Standards in the pharmaceutical industry, including the establishment of the data elements included in the standards, discussion of data element values, and the

formatting of the transaction. I am also a member of the National Association of Chain Drug Stores, the National Community Pharmacists Association, the Academy of Managed Care Pharmacy, and the American Society for Automation in Pharmacy. My colleagues at PHSI and I are active members in these organizations and attend conferences with most of the organizations to both present and stay current with trends and issues that impact the pharmaceutical supply chain.

8. A copy of my CV including authored publications and presentations is attached as **Appendix A**. A list of the expert testimony I have given in the last four years is attached as **Appendix B**.

9. I am compensated at the rate of $650 per hour for my time. Research and analysis for this report was also performed by personnel of Analysis Group, Inc. under my direction and guidance. Neither my compensation nor that of Analysis Group is contingent upon my findings, the testimony I may give, or the outcome of this litigation.

B. Background on the FDA's Valsartan-Containing Drug Recalls

10. Recalls of at-issue valsartan-containing drugs ("VCDs")[1] began in July 2018 when the Food and Drug Administration ("FDA") announced that two manufacturers were voluntarily recalling all lots of non-expired valsartan-containing drugs due to the potential presence of N-nitrosodimethylamine ("NDMA") in the active pharmaceutical ingredient ("API") in drugs supplied by Zhejiang Huahai Pharmaceutical Co. ("ZHP"), Linhai, China.[2] Over the next eight months, four more manufacturers voluntarily recalled

[1] Specifically, there are four VCDs at issue: valsartan, valsartan hydrochlorothiazide ("HCTZ"), amlodipine-valsartan, and amlodipine-valsartan HCTZ. Third Amended Consolidated Economic Loss Class Action Complaint*, In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 1, 2021, ("EL Complaint"), at ¶ 3.

[2] Teva Pharmaceuticals recalled VCD lots labeled as Major Pharmaceuticals and Actavis LLC, and Prinston Pharmaceuticals, Inc. (subsidiary of ZHP) recalled VCD lots labeled as Solco Healthcare LLC. FDA, "FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan), available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan; FDA, "FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity," July 13, 2018, available at https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity.

some or all of their non-expired lots of VCDs.[3] The FDA recommended that patients using the recalled VCDs continue using their medicine until they could obtain a replacement product because valsartan is used to treat serious medical conditions.[4]

11. I understand that the recalls did not involve all valsartan-containing medicines, but instead only those of specific manufacturers, and for some of those manufacturers, only specified lots. As a result, products without the alleged impurities were still being manufactured and sold.[5] I understand that samples from some recalled lots were tested, and the results showed significantly varying levels of NDMA and N-Nitrosodiethylamine ("NDEA"), to the extent there was any at all.

12. The FDA has noted that manufacturers would not have been expected to understand how to test for NDEA and NDMA, nor would they have been expected to test for these compounds as part of their regular quality management processes prior to the FDA's investigation.[6] The FDA stated that "typical tests for API purity, identity, and known impurities are unlikely to detect the presence of a nitrosamine impurity."[7]

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3 These four manufacturers were: Mylan Pharmaceuticals, Inc., Aurobindo Pharma USA, Torrent Pharmaceuticals Limited, and Hetero Labs Limited. FDA, "FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan), available at https://www fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

4 FDA, "FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity," July 13, 2018, available at https://www fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity.

5 FDA, "Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan," February 3, 2021, available at https://www.fda.gov/drugs/drug-safety-and-availability/recalls-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan.

6 FDA, "FDA Statement on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings," August 30, 2018, available at https://www fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-impurities-and-recalls-and-update-fdas-current.

7 FDA, "GENERAL ADVICE," available at https://www fda.gov/media/122643/download.

C. Allegations

13. I understand that Plaintiffs in this matter include consumers and third-party payors ("TPPs") asserting claims for economic loss;[8] consumers asserting claims for medical monitoring;[9] and consumers asserting claims for personal injuries.[10]

14. I understand that Defendants in this matter are API manufacturers,[11] finished dose manufacturers,[12] wholesalers,[13] and retail pharmacies.[14]

15. I understand that Plaintiffs allege that certain Defendants manufactured, sold, labeled, marketed, distributed, and/or dispensed allegedly "misbranded" and/or "adulterated" generic versions of at-issue VCDs in the U.S. from September 2012 until the

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8 Plaintiffs' Memorandum of Law in Support of their Motion for Class Certification of Consumer Economic Loss Claims, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021 ("Consumer Economic Loss Class Certification Memo"); Third Party Payors' Brief in Support of Motion to Certify Class, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021 ("TPP Economic Loss Class Certification Memo").

9 Memorandum of Law in Support of the Medical Monitoring Plaintiffs' Motion for Class Certification, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021 ("Medical Monitoring Class Certification Memo").

10 Consumer Economic Loss Class Certification Memo, p. 2. I am not providing an opinion with respect to the personal injury claims in this matter.

11 Plaintiffs identify four API Manufacturer Defendants and their affiliates: Zhejiang Huahai Pharmaceutical entities (Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai US Inc., Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC, & Solco Healthcare US, LLC.; collectively "ZHP"), Hetero Labs entities (Hetero Labs, Ltd., Hetero Drugs, Limited, Hetero USA Inc., & Camber Pharmaceuticals, Inc.; collectively "Hetero"), Mylan Laboratories entities (Mylan Laboratories, Ltd, Mylan N.V., & Mylan Pharmaceuticals, Inc.; collectively "Mylan"), and Aurobindo Pharma entities (Aurobindo Pharma, Ltd, Aurobindo Pharma USA, Inc., Aurolife Pharma, & LLC.; collectively "Aurobindo"). EL Complaint, at ¶¶ 74-98.

12 Plaintiffs identify two Finished Dose Manufacturer Defendants and their affiliates: Teva entities (Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Arrow Pharm Malta Ltd., Actavis Pharma, Inc., & Actavis, LLC; collectively "Teva") and Torrent entities (Torrent Pharmaceuticals, Ltd. & Torrent Pharma, Inc.; collectively "Torrent"). EL Complaint, at ¶¶ 99-105.

13 Plaintiffs identify three Wholesaler Defendants: Cardinal Health, Inc. ("Cardinal Health"), McKesson Corporation ("McKesson"), and AmerisourceBergen Corp. ("AmerisourceBergen"). EL Complaint, at ¶¶ 148-156.

14 Plaintiffs identify eight Retail Pharmacy Defendants: Walgreens Co. ("Walgreens"), CVS Pharmacy, Inc ("CVS"), Walmart Stores, Inc. ("Walmart"), Rite-Aid Corporation ("Rite-Aid"), Express Scripts, Inc. ("Express Scripts"), The Kroger, Co. ("Kroger"), OptumRx, and Albertson's LLC ("Albertsons"). EL Complaint, at ¶¶ 106-140. I understand that Humana Pharmacy, Inc. is no longer a defendant with respect to the economic loss and medical monitoring class. Expert Declaration of Laura R. Craft, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021, at footnote 8. Although the term Retail Pharmacy Defendants generally includes Express Scripts, it should be clarified that Express Scripts is not a "retail" pharmacy in that it does not have any retail store locations; Express Scripts dispenses prescription medications solely by mail.

recalls of those products starting in July 2018.[15] Plaintiffs claim that Defendants' VCDs were "adulterated and misbranded" compared to their alleged warranties and representations.[16]

16. Plaintiffs allege that the "adulteration" in VCDs began when the API Manufacturer Defendants changed the manufacturing process, which led to the presence of NDMA, NDEA, and potentially other impurities, and that Defendants had notice of the presence of impurities as early as 2011.[17] I understand that the cause, presence (if any), amount (if any), and the timing of the knowledge of the alleged impurities (if any) are in dispute.

17. Plaintiffs seek to certify multiple classes and sub-classes for claims against Defendants. For the consumer economic loss claims, I understand that Plaintiffs seek to certify multiple classes and sub-classes for separate claims, multistate groupings, and Defendant groups, as follows:[18]

- Breach of express warranties against Manufacturer Defendants;
- Breach of implied warranties against Manufacturer Defendants and Retail Pharmacy Defendants;
- Common law fraud against Manufacturer Defendants;
- Consumer protection act claims against Manufacturer Defendants, and against the Retail Pharmacy Defendants […]; and
- Unjust enrichment against Wholesaler and Retail Pharmacy Defendants.

18. With respect to consumer economic loss claims, Plaintiffs specify 93 sub-classes that generally include "individuals […] who […] paid any amount of money for a valsartan-containing drug (intended for personal or household use)" that was manufactured, distributed or sold by any Defendants.[19] For all sub-classes involving Defendants other than Hetero, the class period is "since at least January 1, 2012, and through the date of final recall

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15 EL Complaint, at ¶ 7.

16 EL Complaint, at ¶¶ 392, 396, 624.

17 EL Complaint, at ¶ 6.

18 Consumer Economic Loss Class Certification Memo, p. 55.

19 Plaintiffs' Motion for Class Certification of Consumer, Third Party Payor, and Medical Monitoring Claims, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021 ("Plaintiffs' Motion for Class Certification"), Exhibit A.

(as of November 10, 2021)";[20] for Hetero-specific sub-classes, the class period is "since at least May 1, 2018, and through the date of the final recall (as of November 10, 2021)."[21] The sub-classes for all Defendants exclude:[22]

- Any judge or magistrate presiding over this action and members of their families;
- Defendants and affiliated entities, and their employees, officers, directors, and agents;
- Defendants' legal representatives, assigns, and successors; and,
- All persons who properly execute and file a timely request for exclusion from any Court-approved class.

The sub-classes specific to Retail Pharmacy Defendants and Wholesaler Defendants further exclude "[i]ndividuals whose only valsartan-containing drug purchases (intended for personal and household use), who would otherwise meet this Class Definition, were Hetero Defendants' valsartan-containing drugs dispensed […] prior to May 1, 2018."[23]

19. For TPPs, I understand that Plaintiffs seek to certify a nationwide class defined as:[24]

> A class of all Third-Party Payors that, from at least January 1, 2012 through the date of final recall as of November 10, 2021, paid any amount of money in the United States for a valsartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Active Pharmaceutical Ingredient, Finished Dose or Wholesaler Defendant.

20. Plaintiffs propose 19 TPP sub-classes specific to claims related to breach of express warranties, breach of implied warranties, fraud, violation of state consumer protection laws and unjust enrichment.[25] The TPP class excludes:[26]

- Defendants and affiliated entities;
- Defendants' assigns and successors;

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20 The first generic valsartan HCTZ was available in September 2012; the first generic valsartan was approved in June 2014; the first generic amlodipine valsartan was approved in September 2014; the first generic amlodipine valsartan HCTZ was approved in December 2014. EL Complaint, ¶¶ 7, 279, 281.

21 Plaintiffs' Motion for Class Certification, Exhibit A.

22 Plaintiffs' Motion for Class Certification, Exhibit A.

23 Plaintiffs' Motion for Class Certification, Exhibit A.

24 Plaintiffs' Motion for Class Certification, Exhibit B.

25 Plaintiffs' Motion for Class Certification, Exhibit B.

26 Plaintiffs' Motion for Class Certification, Exhibit B.

- All federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans;
- Pharmacy Benefit Managers ("PBMs");
- TPPs whose only valsartan-containing drug purchases, who would otherwise meet this Class Definition, were for Hetero Defendants' valsartan-containing drugs dispensed prior May 1, 2018; and
- All third-party payors who properly execute and file a timely request for exclusion from any Court-approved class.

21. I understand that, under Plaintiffs' proposed definitions, consumer and TPP economic loss classes would include not only consumers and TPPs who allegedly paid for Manufacturer Defendants' recalled VCDs, but also consumers and TPPs who allegedly paid for Manufacturer Defendants' VCDs that were not the subject of any recall and/or did not contain any alleged impurity.

22. Lastly, I understand that Plaintiffs seek to certify two classes related to medical monitoring claims. Plaintiffs define the Medical Monitoring Independent Claim Class and the Medical Monitoring Remedy Class, respectively, as:[27]

> All individuals residing in Alaska, Arizona, Colorado, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Maine, Massachusetts, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Vermont, West Virginia, Wyoming and who consumed a sufficiently high Lifetime Cumulative Threshold of NDMA, NDEA, or other nitrosamine, in generic valsartan-containing drugs manufactured by or for Defendants and marketed in the United States and its territories and possessions, at least since January 1, 2012. This is the "Medical Monitoring Independent Claim Class."
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> All individuals residing in every state, territory, and possessions of the United States of America except Mississippi who consumed a sufficiently high Lifetime Cumulative Threshold of NDMA, NDEA, or other nitrosamine, in generic valsartan-containing drugs manufactured by or for Defendants and marketed in the United States and its territories and possessions, at least since January 1, 2012. This is the "Medical Monitoring Remedy Class."

[27] Plaintiffs' Motion for Class Certification, Exhibit C.

23. Plaintiffs claim that the definition of the "Lifetime Cumulative Threshold […] is based on objective and ascertainable factors."[28] Excluded from the Medical Monitoring Classes are:[29]

- Defendants and their subsidiaries and affiliates;
- [A]ll persons who make a timely election to be excluded from the Classes to the extent any class is an opt-out class or a hybrid opt-out class;
- [G]overnmental entities;
- [A]ny judicial officers who preside over this case and their immediate family members […]; [and]
- Consumers of VCDs who have been diagnosed with cancers [allegedly] as a result of taking Defendants' NDMA-, NDEA-, or other nitrosamine-contaminated VCDs.

D. Assignment

24. I have been asked by counsel for Defendants to explain the factors and practices in the pharmaceutical industry that affect the amounts paid for prescriptions purchased by and on behalf of consumers who received VCDs, including the pharmaceutical supply chain and various third-party payers; the complexities that would be relevant to the assessment of injury on a class-wide basis in this matter; the extent to which available data allow for the identification of class members as well as those who are excluded from the class definitions; the extent to which available data allow for the calculation of the amount of impurities to which a patient may have been exposed; and the extent to which data are available and sufficient to reliably estimate damages on a class-wide basis in the event any Defendants are found liable.

[28] Plaintiffs' Motion for Class Certification, Exhibit C.

[29] Plaintiffs' Motion for Class Certification, Exhibit C.

25. As part of this assignment, I have also been asked to review and comment on the expert declarations of Rena Conti,[30] Laura Craft,[31] and Kali Panagos[32] submitted in connection with Plaintiffs' motion for class certification, as they relate to the scope of my work described above.

26. To prepare this report, I reviewed numerous materials including:

a. Plaintiffs' expert declarations, including all produced data sources and documents relied upon;

b. Plaintiffs' and Defendants' scientific expert reports and depositions;

c. Declarations and depositions of Defendant fact witnesses;

d. Depositions of consumer and TPP class representatives, assignors to MSP Recovery Claims, and other interested parties, such as Anthem Health Plans of Maine, Inc. ("Anthem"), Maine Automobile Dealers Association, Inc.'s ("MADA") third-party administrator;

e. Court filings pertaining to this litigation including the Third Amended Consolidated Economic Loss Class Action Complaint, Defendants' responses to requests for production, and Plaintiffs' motions for class certification and memoranda in support of class certification;

f. Data and documents produced by Named Plaintiffs, including MSP Recovery Claims and its assignors, MADA, and Anthem; and

g. Data produced by Retail Pharmacy Defendants.

27. In addition to the materials described above, I relied on publicly available information, including books and academic articles, websites, statutes and regulations, and

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30 Expert Declaration of Rena Conti, Ph.D., *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021 ("Conti Declaration").

31 Expert Declaration of Laura R. Craft, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021 ("Craft Declaration").

32 Expert Report of Kali Panagos, Pharm.D., R.Ph., *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021 ("Panagos Declaration").

financial documents. The sources on which I relied in reaching my opinions are listed in the attached **Appendix C**. I have also drawn upon my knowledge and more than 38 years of experience in the pharmaceutical industry with pharmacy network contracting, pharmaceutical benefit design, P&T committees, and claims processing system capabilities. I understand that discovery is ongoing. Should additional relevant documents or information be made available to me, I may adjust or supplement my opinions as appropriate.

II. Summary of Opinions

28. On the basis of my experience, knowledge, and review of evidence, I have reached the opinions discussed below.

29. Plaintiffs' experts have put forth opinions and proposed methodologies based on overly simplistic views of the pharmaceutical industry. In reality, the pharmaceutical industry is highly complex. As I discuss in **Section III**, the pharmaceutical supply chain involves many different intermediaries that hold individual contractual arrangements, which govern the distribution of and payment for pharmaceutical products, including generic VCDs. There are numerous types of payors that offer pharmacy benefit programs, and each of these payors may structure their pharmacy benefit programs differently, depending on their PBM, formulary management strategy, contracted retail pharmacy network, availability of mail-order pharmacy services, and their benefit design and cost-sharing arrangements. Payment for a single prescription fill of VCDs can be shared across multiple parties, including a health plan or insurance company, a consumer, and federal and state governmental entities (which are excluded from the proposed classes). For example, for Medicare Part D plans, such as those assigned to Named Plaintiff MSP Recovery Claims, the federal government provides TPPs with payments that are expected to cover almost three-quarters of plan prescription costs and provides additional payments for patients depending on the coverage phase. As a result of this complex pharmaceutical system, identifying the relevant members of the proposed classes and sub-classes, tracing the amount paid from the point of sale back through the supply chain to individual Defendants, and estimating damages for these classes require accounting for many nuances that Plaintiffs' experts ignore.

30. The involvement of numerous entities in the pharmacy benefit payments flow and the many individual contracts between entities mean that obtaining, combining, and analyzing data to identify consumer and TPP members of the proposed classes and sub-classes, and then applying the class exclusions accurately, is a time-consuming and burdensome process that cannot be done in a reliable and administratively feasible manner (i.e., a programmatic or systematic manner that does not require extensive manual review). Ms. Craft merely identifies different potential sources of data for this process but fails to recognize the many limitations of the available data produced in this matter, and she does not propose a methodology to utilize the data to identify class inclusions/exclusions. As I demonstrate in **Section IV**, the available data are insufficient for identifying proposed class members in a systematic manner because:

a. The data produced in this matter demonstrate that identification of class members requires individualized inquiry. For the proposed TPP class, there is no data source that consistently identifies the final payor for prescription claims and that clearly distinguishes between the final payor and any intermediaries that may be facilitating the claims processing. As a result, proposed TPP class members cannot be identified without individually investigating entities appearing in the claims data.

b. For the proposed medical monitoring classes, the produced data are insufficient for accurately determining the cumulative levels of NDMA and NDEA to which consumers were exposed, if any, as a result of their VCD prescriptions.

c. The limitations inherent in the data produced in this matter prevent class exclusions from being applied without individualized review. For example, state government entities are not readily identifiable, and the unique nature of this case requires identification and exclusion of potentially hundreds of thousands of individual Defendant employees across many different data sources. Ms. Craft fails to consider the nuances of applying these exclusions.

d. Data elements necessary to identify proposed class members, such as lot number information and expiration date, do not exist throughout the pharmacy supply chain down to the patient level for the entire class period. The lack of these data elements

makes it difficult, if not impossible, (i) to identify specific lots with specific expiration dates that were recalled at the patient level, (ii) to determine whether a wholesaler, and if so, which one, was involved in the distribution of a VCD prescribed to a patient, and (iii) to assess whether consumers meet the proposed medical monitoring class definitions.

e. Ms. Craft does not provide any methodology for combining information across many disparate systems where no universal patient identifier or data map exists. Importantly, she fails to acknowledge that matching patient records within the same organization requires extensive manual review, let alone matching across different organizations. Ms. Craft also fails to acknowledge that obtaining the necessary data to identify proposed class members would not be administratively feasible because such data are held by different entities across the pharmaceutical industry in many different formats and are closely guarded and kept in secrecy.

31. The multitude of pharmacy benefit programs offered by the numerous TPPs and the contractual arrangements that govern the payment amounts are particularly relevant to any assessment of damages. However, Dr. Conti ignores these complexities and presents a damages model that generates results inconsistent with the realities of the pharmaceutical industry. As I explain in **Section V**:

a. Dr. Conti's damages model is predicated on her conclusion that the at-issue VCDs are worthless. However, this conclusion is inconsistent with how the pharmaceutical industry assesses the value of maintenance drugs, such as VCDs, and is contradicted by the FDA guidance during the recalls as well as the testimony of the class representatives: that the at-issue VCDs were effective in treating hypertension and/or heart failure notwithstanding any impurities and therefore conferred clinical value to proposed class members.

b. If the at-issue VCDs had not been purchased by proposed consumer and TPP class members, as Dr. Conti suggests, these proposed class members would have incurred other costs: either costs associated with the adverse health effects of not treating hypertension and/or heart failure or costs associated with the purchase of alternative therapies. Most likely, proposed class members would have purchased

one or more of the many alternative anti-hypertensive medications available to achieve the efficacy that they received from purchasing the at-issue VCDs and to mitigate the higher costs associated with adverse health outcomes. From a business perspective, determining whether the costs borne by class members would have been any different requires a significant amount of information, including (1) the amounts paid for at-issue VCD prescriptions by each party, which vary substantially; (2) whether those prescriptions would have been different (i.e., written for a different treatment), which may vary across beneficiaries and their healthcare providers; and (3) whether the prices that *would have been* paid by the various parties to the transaction are lower, higher, or the same as the amount that had been paid for the at-issue VCD prescriptions, which vary across pharmacy benefit programs. Dr. Conti fails to account for any of these offsetting costs.

c. Dr. Conti's analysis inappropriately ignores the outsized role of government payors—i.e., parties that are excluded from the proposed classes—in the purchase of prescription drugs indicated for the treatment of hypertension and heart failure, such as the at-issue VCDs. She also proposes no method by which to determine the portion of costs that were borne by proposed class members as opposed to those government entities. As such, her proposed calculations vastly overstate the costs to proposed class members and their alleged damages.

d. The entities involved in the pharmaceutical supply chain have mechanisms in place to issue refunds and credits in the event of a recall. Dr. Conti fails to account for any such refunds and credits that were issued by Defendants.

e. While I offer no opinion on the legal definition of "unjust enrichment," Dr. Conti's calculation of Retail Pharmacy Defendants' unjust enrichment and her proposed, but not implemented, methodology for calculating Wholesaler Defendants' unjust enrichment are inconsistent with how the pharmaceutical industry views costs and profits. Moreover, they do not provide any indication of whether or the extent to which a pharmacy or wholesaler earned a profit on the sale of a prescription or on the wholesaler's sale of inventory to a pharmacy. Dr. Conti's proposed methodologies fail to account for the complexities inherent in the numerous

contractual relationships that would inform the revenues and costs for either Retail Pharmacy Defendants or Wholesaler Defendants associated with individual consumer Plaintiffs' copayments or TPP members' covered claims (e.g., pharmacy network agreements, wholesaler vendor agreements, and various purchasing agreements, all of which impact the price paid at each level of the pharmaceutical supply chain). Specifically, for her calculation of Retail Pharmacy Defendants' unjust enrichment, Dr. Conti ignores costs associated with pharmacies' business models—including the ingredient cost paid by the pharmacy to purchase the product, labor costs to dispense the product, rent and operating costs—and consequently, she vastly overstates any measure of profits. For her proposed method of calculating Wholesaler Defendants' unjust enrichment, Dr. Conti has not identified all wholesaler costs for which she would account.

32. Lastly, as I discuss in **Section VI**, Dr. Panagos presents an overly simplified view of P&T committees' decision-making process and mischaracterizes the purpose of the Orange Book and how it is used in standard industry practice. Based on my experience, the Orange Book is just one source that P&T committees may consult, and TPPs do not consider information in the Orange Book to "represent a manufacturer's warranty."

III. Complexities of the Pharmaceutical Industry that are Relevant to Assessing Economic Loss and Identifying Economic Loss and Medical Monitoring Class Members

33. I understand from Counsel that Plaintiffs have the burden of demonstrating that the members of the proposed economic loss and medical monitoring classes can be identified (i.e., the class members are ascertainable). I further understand that Plaintiffs must provide an accurate and reliable method for demonstrating injury and estimating damages, if any, on a class-wide basis using common evidence and a common methodology.

34. In this matter, the members of the proposed economic loss classes allegedly paid more for VCDs than what they claim the VCDs were worth. Any methodology for determining the amount that these proposed class members paid for the at-issue VCDs, what would have been paid for alternative medications, and for identifying the proposed economic loss and medical monitoring class members requires an understanding of the characteristics of the industry, the types of payors, the dimensions along which pharmacy

benefit programs vary, and the role of non-class members (e.g., government payors) in the payment for VCDs. In this section, I explain the complexities of the pharmaceutical industry and their relevance for an assessment of economic loss.

A. The Flow of Products and Pharmacy Benefit Payments for Generic Drugs Is Complex

35. Brand drug medications are approved through a New Drug Application ("NDA")[33] process or a Biologics Licensing Arrangement ("BLA")[34] established by the FDA. Generic drugs, like the at-issue VCDs, are typically approved through an Abbreviated New Drug Application Process ("ANDA"). Brand and generic products available for use in the United States are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), and this list is maintained and continually updated by the FDA.[35] I focus my discussion in this section on generic products.

36. Before a generic prescription medication reaches a patient, the participants in the pharmaceutical supply chain transfer ownership of the medication from a drug manufacturer to an individual consumer through various intermediaries.[36] The *distribution* of a generic medication involves multiple market participants, and there are multiple channels through which a generic product may reach the consumer (i.e., the patient): the manufacturer may sell (1) through a wholesaler that resells the product to a pharmacy; (2) directly to a retail pharmacy; or (3) directly to a mail service pharmacy. The consumer purchases the generic product from a retail or mail order pharmacy. The use of multiple purchasing channels for generic drugs, such as VCDs, complicates the ability to identify members of the proposed sub-classes that require determining whether a specific wholesaler was part of the distribution chain, as I discuss further in **Section IV.C**.

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33 FDA, "New Drug Applications (NDA)," available at https://www.fda.gov/drugs/types-applications/new-drug-application-nda.

34 FDA, "Biologics License Applications (BLA) Process," available at https://www fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber.

35 FDA, "Abbreviated New Drug Applications (ANDA)," available at https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda; FDA, "Frequently Asked Questions on The Orange Book," February 5, 2020, available at https://www.fda.gov/drugs/drug-approvals-and-databases/frequently-asked-questions-orange-book.

36 Government Accountability Office, "Generic Drugs Under Medicare," August 2016, at p. 6, available at https://www.gao.gov/assets/gao-16-706.pdf.

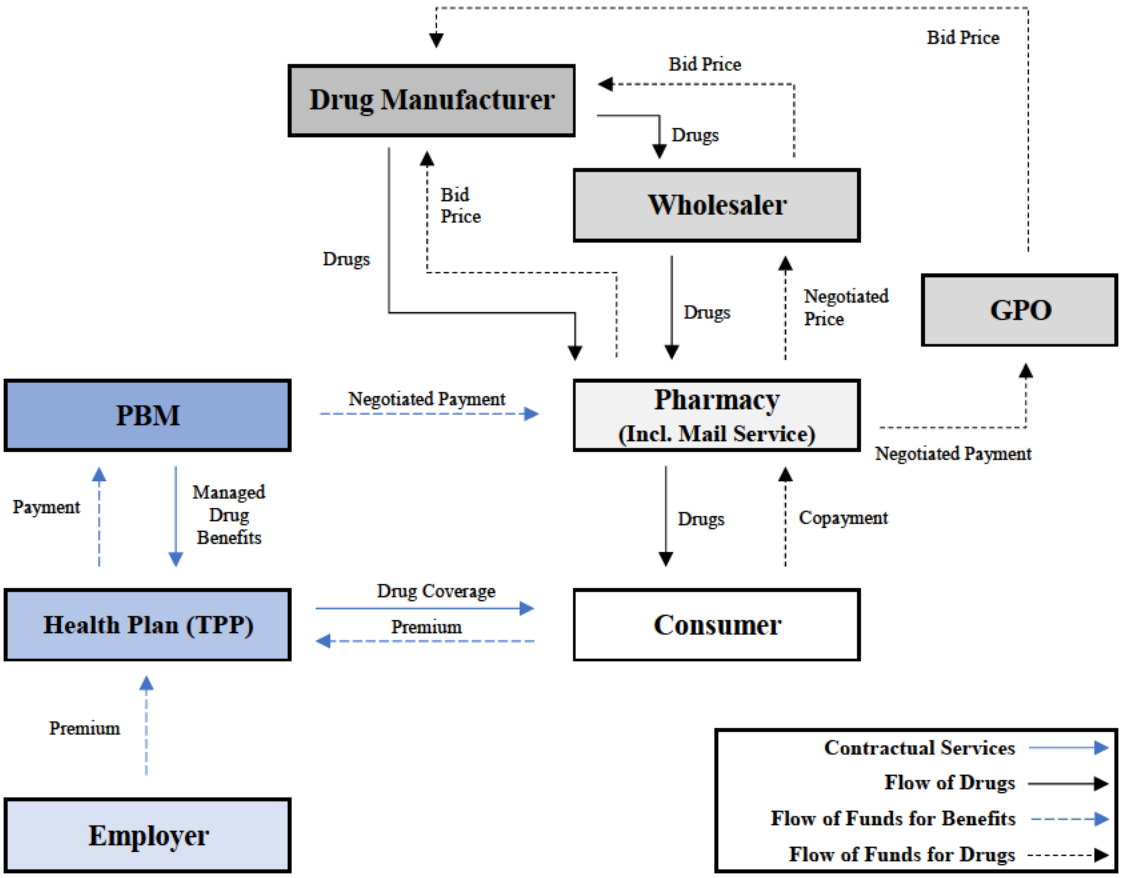
37. The *payment* for a generic medication is even more complex. Payment flows related to how consumers receive coverage and pay for their prescriptions along the pharmaceutical supply chain—called the pharmacy benefit payment flow—are governed by a complex set of negotiated prices and market transactions. In addition to manufacturers, wholesalers, and pharmacies, the pharmacy benefit payment flow may involve additional market participants that do not take ownership of the physical product, including TPPs, such as healthcare plan sponsors, government payors, and PBMs.[37]

38. In the vast majority of transactions covered in whole or in part by insurance, there is no single party bearing the full cost of the prescription, and the share of costs borne by each party varies across prescriptions depending on the specific characteristics of the pharmacy benefit program, the drug dispensed, the formulary, the patient's out-of-pocket costs for other prescription drugs, and the price set by the PBM. As I discuss in greater detail in **Section III.C** below, as a result of the individual contracts among different entities involved in the pharmaceutical supply chain, the price that a TPP ultimately pays for each prescription of a generic drug varies substantially across generic drugs, PBMs, patients, and individual transactions.

39. **Figure 1** below shows a sample flow of funds to pay for a generic drug purchased at a retail or mail order pharmacy and managed by a PBM for an employer's fully insured health plan, and I describe the role of each entity in greater detail below. The payment flows in **Figure 1** are designated by dashed lines.

[37] Government Accountability Office, "Generic Drugs Under Medicare," August 2016, available at https://www.gao.gov/assets/gao-16-706.pdf.

Figure 1
Example Flow of Products and Payments Along the Pharmaceutical Supply Chain for Generic Drugs[38]



40. Starting at the bottom of **Figure 1** working up, the relevant parties and elements to prescription drug reimbursement are:

a. An employer contracts with a health plan (such as Aetna, which is the TPP class member in this example) to provide a fully insured pharmacy benefit to its employees and beneficiaries (i.e., the consumer class members in this example) in exchange for a fixed premium. The employer selects its pharmacy benefit plan among many different pharmacy benefit options offered by the health plan. Under its contract with the employer, the TPP is required to provide coverage for beneficiaries in accordance with the plan's pharmacy benefit design documents.

[38] Government Accountability Office, "Generic Drugs Under Medicare," August 2016, available at https://www.gao.gov/assets/gao-16-706.pdf (adapted from Figure 1).

b. The consumer is responsible for a copayment or coinsurance[39] paid to the retail pharmacy or the mail order pharmacy based on their pharmacy benefit program, as well as premium payments to their employer that are passed through to the health plan. The cost sharing between the consumer and the TPP depends upon the point-of-sale price (which is determined by negotiated contracts upstream, described further below), as well as coverage specified in their health plan, the type of pharmacy used, and potentially the phase of benefit coverage they are in during the year. I discuss these numerous dimensions of pharmacy benefit programs that impact the costs borne by the TPP and the consumer in more detail in **Section III.C**.

c. The health plan may contract with a PBM to manage its pharmacy benefits. PBMs are companies that administer pharmacy benefits and provide pharmacy network and formulary services to their clients, which can include TPPs that provide prescription drug benefits to consumers, such as self-insured and fully insured commercial health plans and Medicare Part D plans. PBMs provide a variety of services including formulary management, pharmacy network contracting, claims processing,[40] utilization management, and mail-order and specialty pharmacies. Health plan contracts are individualized and differ across PBMs, as discussed in detail in **Section III.C**. In some cases, an employer may self-insure and contract directly with a PBM or through an intermediary, such as a third-party administrator ("TPA") or an insurer providing administrative services only ("ASO") which in turn subcontracts with a PBM. Under this arrangement, the self-insured employer is responsible for paying the prescription drug claims of its employees and dependents and thus functions as a TPP.[41] PBMs differentiate their services and offer specialized service and product offerings specific to their TPP clients.[42]

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39 Consumers may pay a fixed amount ("copay") per prescription or a fixed share of the prescription's negotiated price ("coinsurance").

40 When an insured consumer fills a prescription at a pharmacy, a claim is submitted to request payment from the health plan for prescription drugs covered by health plan's pharmacy benefit.

41 I discuss additional types of payors in more detail in **Section III.B**.

42 Pharmaceutical Care Management Association, "Testimony to the ERISA Advisory Council," August 20, 2014, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure-kanwit-08-20.pdf, at p. 3 ("It's a truism that 'when you've seen one PBM/plan sponsor contract, you've seen one PBM/plan sponsor contract.' The reason is that PBM

d. PBMs contract with pharmacies through pharmacy network agreements that include drug pricing for brand and generic products. The PBM may offer pharmacies the ability to participate in multiple pharmacy networks, and the number of pharmacies in a given network impacts the level of price discounts. Narrow or closed networks offer the lowest prices because pharmacies are willing to accept lower reimbursement for increased prescription volume. Open pharmacy networks generally have higher reimbursement rates because any pharmacy that agrees to the terms and conditions of the PBM's pharmacy network agreement is allowed to participate.[43] There are costs and fees that are incurred for every prescription drug dispensed. These costs and fees vary depending on the highly confidential pricing and contractual terms negotiated between PBMs and pharmacies.[44] These specific costs and fees negotiated are:

i. *Ingredient cost:* A PBM typically establishes a maximum allowable cost ("MAC" price) to reimburse pharmacies for multi-source generic drugs, such as VCDs. In general, a PBM creates a single MAC price that it will pay to pharmacies for a particular generic product regardless of the manufacturer. The PBM will reimburse a pharmacy at one MAC price for any generic VCD, even if the pharmacy purchases the generic VCD from multiple manufacturers that each charge the pharmacy a different price for their product. MAC pricing is used to incentivize pharmacies to procure generics from lower-cost manufacturers.[45] PBMs develop MAC prices based on a variety of factors, such as the number of generic suppliers, the length of time of the generic has been on the market, product shortages or

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contracts comprise a highly diverse set of arrangements, depending on the particularized and varying requirements of thousands of PBM customers — the plan sponsors and employers who rely on their services.").

43 *See, e.g.,* Retailer Pharmacy Defendants' Letter Re: Macro Discovery Disputes, *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, Case No. 1:19-md-02875-RBK-JS, June 16, 2020 ("Retailer Pharmacy Defendants' Letter"), Exhibit J (Declaration of Megan Mistarz, Senior Director of Payor & Provider Solutions at Walgreens, May 18, 2020) at ¶ 7.

44 *See, e.g.,* Retailer Pharmacy Defendants' Letter, Exhibit K (Declaration of Michael Viirre, Senior Director of Specialty Pharmacy at Walmart, May 13, 2020) at ¶¶ 5-7.

45 Fry, Scott, et al., "What Is the Price Anyway?" The Actuary, May 2020, available at https://theactuarymagazine.org/what-is-the-price-anyway/.

recalls, and whether a pharmacy is in or out of network.[46] MAC prices may also vary from health plan to health plan.[47] PBMs change MAC prices throughout the year; for example, CVS Health states that it adjusts MAC prices to "reflect current marketplace pricing and [its] best understanding of the marketplace and product availability."[48] MAC prices are considered highly proprietary by both PBMs and pharmacies and are identified as highly confidential information.[49]

ii. *Dispensing fees:* PBMs and pharmacies also negotiate a dispensing fee, which is typically a flat amount paid for each prescription filled.[50] Dispensing fees do not typically vary based on the particular drug dispensed (e.g., the pharmacy would be paid the same dispensing fee for a prescription for valsartan and for irbesartan), but they often vary based on the drug formulation (e.g., injectable vs. tablet) and differ from plan to plan and pharmacy to pharmacy. [redacted][51] Determining the dispensing fee incurred for any prescription drug

46 Academy of Managed Care Pharmacy, "Maximum Allowable Cost (MAC) Pricing," May 2019, available at https://www.amcp.org/policy-advocacy/policy-advocacy-focus-areas/where-we-stand-position-statements/maximum-allowable-cost-mac-pricing.

47 Association for Accessible Medicines, "Introduction to the Generic Drug Supply Chain and Key Considerations for Policymakers," 2017, available at https://accessiblemeds.org/sites/default/files/2017-10/AAM-Generic-Brand-Drug-Supply-Chain-Brief.pdf, p. 8.

48 CVSHealth, "Our Maximum Allowable Cost (MAC) Pricing is a Commonly Used Tool to Manage Drug Costs," available at https://cvshealth.com/news-and-insights/articles/our-maximum-allowable-cost-mac-pricing-is-a-commonly-used-tool-to-manage.

49 *See, e.g.,* Retailer Pharmacy Defendants' Letter, Exhibit C (Declaration of Grace Allen, Vice President of Client Pricing and Underwriting at Express Scripts, June 2, 2020) at ¶¶ 8-10.

50 Association for Accessible Medicines, "Introduction to the Generic Drug Supply Chain and Key Considerations for Policymakers," 2017, available at https://accessiblemeds.org/sites/default/files/2017-10/AAM-Generic-Brand-Drug-Supply-Chain-Brief.pdf, p. 5.

51 ANTM_MADA_SUBP_00002229-2258 at 2257-2258.

claim therefore requires examining each TPP's contract with its PBM or ASO, as well as the particular terms of the contractual relationships between the PBM or ASO the pharmacy that dispenses that prescription to the consumer.

iii. *Generic effective rates:* PBMs may also negotiate a generic effective rate ("GER") for overall generic drug reimbursements with retail pharmacy chains and pharmacy service administrative organizations ("PSAOs"), the latter of which negotiate on behalf of independent and small chain pharmacies. A GER is a market-basket approach to pricing, in which the cost of *all* generic drugs reimbursed by the PBM over a certain time frame should equal a certain percent discount off of the Average Wholesale Price ("AWP").[52] Because pricing is determined based on the prices of other drugs reimbursed by the PBM, the price paid for a single prescription may be higher or lower than the contractually negotiated GER as long as the average discount across all prescriptions reimbursed by the PBM is equal to the GER rate. If a pharmacy receives reimbursements greater than the contracted GER, "the PBM will adjust the reimbursements, either at point-of-sale on future claims or at remittance, to match the contracted rate."[53] Determining the price for any generic medication therefore requires reviewing specific contracts between PBMs and pharmacies to determine whether the point-of-sale price accurately reflects the net price paid to a pharmacy or whether collecting additional information on remittances is necessary.

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[52] Amplicare, "What GER Means for Pharmacies," April 25, 2019, available at https://www.amplicare.com/articles/what-gers-mean-for-pharmacies. Although AWP is used to describe the average price paid by a retailer to purchase a drug from a wholesaler, it is typically considered to be the retail list price in the industry that is rarely actually paid by any single retailer. The calculation of AWP is not clearly defined, but it has long been used by both government and private payers as a benchmark off of which to determine the pricing of prescription drugs. Anderson, Leigh Ann, "Average Wholesale Price (AWP) as a Pricing Benchmark," Drugs.com, September 23, 2020, available at https://www.drugs.com/article/average-wholesale-price-awp html.

[53] Amplicare, "What GER Means for Pharmacies," April 25, 2019, available at https://www.amplicare.com/articles/what-gers-mean-for-pharmacies.

iv. *Adjustments after the point-of-sale transaction:* PBMs may also assess fees after a prescription is filled. For example, direct and indirect remuneration ("DIR") fees are specific to Medicare Part D plans, such as the plans placed at issue by MSP.[54] PBMs charge DIR fees, which are typically deducted retrospectively, for negotiated performance reasons, or for participation in a pharmacy network.[55] The PBM may also provide retail pharmacy network guarantees to their TPP clients based on the weighted average discount agreed upon for a market basket of generic drugs tied to each TPP's utilization.[56] Because DIR fees are not allocated on a drug-by-drug basis, determining whether prices were retroactively reduced for certain prescriptions, such as VCDs, would require information about all generic drugs purchased at a pharmacy by a TPP's members to allocate fees and estimate the net price paid for prescriptions.

e. Pharmacies may contract with wholesalers, directly with generic drug manufacturers, or through generic buying groups (also known as group purchasing organizations, "GPOs") to purchase products to dispense to consumers. For example, [redacted][57]

f. Wholesalers sign supply agreements to purchase drugs from generic manufacturers to stock wholesalers' warehouses.[58] Wholesalers sign separate supply agreements to sell medications to pharmacies. Pharmacies place orders with wholesalers and

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54 *See, e.g.,* MSP 0001152-1172 at 1154 [redacted]

55 National Community Pharmacists Association, "Frequently Asked Questions (FAQs) about Pharmacy 'DIR' Fees," available at http://www ncpa.co/pdf/dir-faq.pdf.

56 *See, e.g.,* Retailer Pharmacy Defendants' Letter, Exhibit K (Declaration of Michael Viirre, Senior Director of Specialty Pharmacy at Walmart, May 13, 2020) at ¶ 5.

57 Deposition of Susan Peppers, Vice President of Pharmacy Practice at Express Scripts, September 28, 2021, pp. 30:4-31:21.

58 *See, e.g.,* Deposition of Martin Igel, Vice President of Global Sourcing at Cardinal Health, October 5, 2021 ("Igel Deposition"), p. 140:4-11.

generic manufacturers to maintain inventory levels to avoid stock-outs at each dispensing location.[59] Pharmacies are thus able to fill consumers' prescriptions without needing to wait for orders from their suppliers, minimizing consumers' wait times. Therefore, the sales of generic medications among manufacturers and wholesalers, wholesalers and pharmacies, and manufacturers and pharmacies are based on individually negotiated agreements and occur prior to the point at which a consumer receives their prescription. The complex claims adjudication process takes place during the dispensing process to determine the pharmacy reimbursement and the costs of the prescription that are to be paid by the consumer and/or the TPP, based on the factors discussed in **Section III.C**. Based on current industry practices, which I describe in **Section IV.C**, it is not possible to determine all of the various intermediaries in the pharmacy supply chain that took possession of and were involved in the ultimate sale and distribution of each individual tablet dispensed to consumers.

g. Generic manufacturers sell their products to pharmacies, wholesalers, hospitals, and clinics. When generic manufacturers contract directly with a pharmacy chain, they may provide additional purchase discounts. For example, [redacted][60] If multiple drug manufacturers manufacture and sell a generic product, pharmacies and wholesalers may have separate supply contracts with, and purchase their generic products from, more than one generic manufacturer.[61] Pharmacies may negotiate the ability to buy products "off contract," i.e., separate from their prime vendor wholesaler agreement. Pharmacies may ask generic manufacturers to bid on products to secure inventory that lowers their cost of goods as compared to the

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59 *See, e.g.,* Deposition of Steven Taylor, OptumRx, October 7, 2021("Taylor Deposition"), pp. 257:3-268:15.

60 Deposition of Daniel Brais, Director of Pharmaceutical Manufacturer Relations at Humana, September 28, 2021 ("Brais Deposition"), p. 46:4-16 [redacted].

61 *See, e.g.,* Retailer Pharmacy Defendants' Letter, Exhibit B (Declaration of John Holderman, Senior Director of Pharmacy Merchandising at CVS, June 12, 2020) at ¶ 6.

prices offered by their wholesaler. Because the same drug can be purchased across different channels at different prices at any given point in time, the acquisition cost of a VCD will vary widely across pharmacies based on their business mix, wholesaler strategy, and willingness to procure generic products off contract. The individually negotiated agreements among various manufacturers, wholesalers, and pharmacies result in a complex cost structure that inform the profits earned by these parties, if any, on sales of individual prescriptions.

41. In summary, the contracts between the employer and the health plan, the health plan and the PBM, the PBM and the pharmacy, the pharmacy and wholesalers, the pharmacy and generic manufacturers, and wholesalers and manufacturers are separately negotiated, and result in the flow of funds for the pharmacy benefit. Each contract in the pharmacy benefit flow is negotiated individually among the relevant parties, and, and these contracts collectively impact (1) the payments wholesalers make to manufacturers for generic drugs; (2) the prices paid by pharmacies to wholesalers and/or manufacturers for their stock of generic drugs; (3) the total payments that pharmacies receive for a prescription; and (4) the share of that prescription cost that will be paid by consumers, and the amount paid by a TPP. The characteristics of each individual contract along the pharmacy benefit payment flow are unique to the parties in the contract, which results in significant variation in prices paid by TPPs and consumers for the same medications. Moreover, in many cases, the prices paid for prescriptions can be retroactively adjusted, which further complicates the determination of the actual costs that were borne by the various parties to a transaction. In short, accurately determining the price paid for a VCD prescription and the parties sharing the cost of a VCD prescription requires individualized inquiry into the business relationships among the multiple parties involved in the purchase and distribution of generic drugs. This analysis cannot be done in the aggregate, without review of the unique circumstances governing each individual transaction.

B. Numerous Types of Payors Offer Pharmacy Benefit Programs

42. While **Section III.A** provided just one example of a payor—a health plan providing fully insured health benefits to consumers—there are many different types of payors that provide prescription coverage to consumers as specified in the payors' pharmacy

benefit plan documents at the beginning of each benefit year. I understand that Plaintiffs contend that a subset of these payors constitute TPPs under the proposed TPP class definition. The variety of payors in the industry results in there being substantial variation in the prices paid by TPPs for the same generic product and a need to assess each TPP's funding to determine the payor(s) that bear(s) the costs for any given prescription drug claim.

43. Payors that may offer a pharmacy benefit include, among others, self-insured employers; fully insured employers; union plans organized as employee welfare benefit plans under the Employee Retirement Income Security Act of 1974 ("ERISA"); plans purchased by individuals through the Affordable Care Act ("ACA") Healthcare Exchange ("HIX"); Medicare Part D plans; Medicare Advantage plans; and Medicaid managed care plans.

44. These various types of TPPs cover the majority of consumers' VCD prescriptions. **Table 1** below summarizes the share of at-issue VCD prescriptions covered by the different types of payors, based on the IQVIA Xponent data relied on by Plaintiffs' experts and the list of VCDs recalled by the FDA, identified by National Drug Codes ("NDCs")[62] used by Dr. Conti.[63] [redacted][64]

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62 An NDC is a unique, 11-digit number used by the FDA to identify drugs. The number consists of three segments identifying the manufacturer, the specific drug product, and the product package size. FDA, "National Drug Code Directory," December 18, 2020, available at https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory; Arizona Health Care Cost Containment System, "National Drug Code (NDC)," January 12, 2017, available at https://www.azahcccs.gov/Resources/Downloads/DFMSTraining/2017/NationalDrugCode.pdf, p. 1.

63 IQVIA is a third-party industry data solutions provider, and describes the Xponent data as a dataset that "[p]rovides detailed prescriber level prescription information for the U.S., including dispensed drug prescription information from retail pharmacies (chain, mass merchandisers, independent, and food stores), mail service pharmacies, and long-term care facilities." IQVIA, "Available IQVIA Data," available at https://www.iqvia.com/insights/the-iqvia-institute/available-iqvia-data.

64 IQVIA's classifications of payors are not always accurate and can be too aggregated for the purposes of identifying relevant TPP class members. I discuss these issues in detail in **Section IV.A**.

Table 1
Share of At-issue VCD Prescriptions by Type of Payor[65]

Payor	2013	2014	2015	2016	2017	2018	2019
[redacted]	1	1	1	1	1	1	1

45. TPPs have different healthcare motivations and financial constraints, which arise from the results of collective bargaining for union plans, competition for employees for private employers, and the interaction of regulation and competition for Medicare Part D plans. These differences impact the design of, and negotiations for, their pharmacy benefit, which I discuss further in **Section III.C**. Importantly, these differences also lead to the involvement of different intermediaries and entities that may assist in paying for prescription drug costs, such that identifying the relevant TPP class member (i.e., the entity ultimately responsible for the prescription drug costs) requires understanding the specific contracts into which each payor has entered, rather than mere reliance upon pharmacy claims data.

1. Employment-Based Coverage

46. **Self-insured Employers:** Self-insured employers typically have a sufficiently large employee base and the financial strength to accept the risk of paying the claims arising from their pharmacy benefit program. In 2018, 61 percent of all covered workers in the U.S. were enrolled in either partially or fully self-funded health plans (13 percent of covered workers in small firms and 81 percent of covered workers in large firms).[66] These employers may purchase catastrophic coverage that limits their risk for very high-cost patients. Self-insured employers create their pharmacy benefit programs based on their strategy for managing employee health benefit costs. They contract with a health plan

65 Backup calculations to this report.

66 Claxton, Gary et al., "Employer Health Benefits, 2018 Annual Survey," Kaiser Family Foundation, available at https://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018, p. 12. Small firms are defined as those with 3-199 workers, while large firms have 200 or more workers.

or PBM to administer their program, or with TPAs that aggregate claims volume from multiple employers and contract with PBMs on their behalf, but the self-insured employer remains ultimately responsible for paying pharmacy claims to the extent not covered by its catastrophic coverage. A company like Amazon is an example of a self-insured employer, which contracts with insurers providing ASO services, such as Aetna, to administer Amazon's health benefits and process claims.[67] Self-insured employers would be members of the proposed TPP classes under Plaintiffs' proposed class definitions.

47. **Fully Insured Employers:** Small employers typically do not have the financial strength to self-insure their pharmacy benefit program, and instead purchase a fully insured healthcare product from a health plan or insurance company, which bears the financial risk. Small employers with fully insured plans pay a defined, flat premium for their employees' healthcare costs, but do not pay the costs of each pharmacy claim. Small employers also have the option to contract with TPAs or through employee benefit consultant brokers that can obtain prescription drug coverage on the employer's behalf. By contracting with a TPA or broker, the employer leverages the collective volume of prescriptions purchased by all companies represented by the TPA and/or broker to obtain more cost-effective coverage. Under Plaintiffs' proposed class, the insurance company that bears the risk for prescription drug costs, not the fully insured employer, would be a member of the proposed class.[68] EmblemHealth, SummaCare, and ConnectiCare—assignors to MSP—provide a range of funding options to clients, including fully-insured health benefits and ASO options.[69] Where EmblemHealth, SummaCare, and ConnectiCare provide fully-

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67 Goforth, Alan, "Amazon Care Reportedly Seeking to Partner with Major Insurers," July 13, 2021, available at https://www.benefitspro.com/2021/07/13/amazon-care-reportedly-seeking-to-partner-with-major-insurers/?slreturn=20211128134948#:~:text=Amazon%20self%2Dinsures%20its%20employee,to%20work%20with%20Amazon%20Care.

68 *See* Craft Declaration, at ¶ 63 ("Only those entities that 'paid any amount of money for a valsartan-containing drug (intended for personal or household use)' meet the primary condition of the Class definitions. Fully-insured plans make no such payments. Instead, these entities purchase their prescription drug coverage from a third-party insurance provider (e.g., Aetna, United Health Care, Blue Cross Blue Shield) that takes on all financial responsibility for claims; these providers therefore become members of the Class.").

69 EmblemHealth, "Why EmblemHealth?" available at https://www.emblemhealth.com/employers/about; SummaCare, "Fully-Insured Products," available at https://www.summacare.com/employer-sales/fully-insured-products; ConnectiCare, "Employer Plans" available at https://www.connecticare.com/employers/plans.

insured health benefits, these entities may have borne the costs of some prescriptions; where they provide ASO services, they did not bear any costs associated with drug prescriptions.

48. **Other Employment-based Plans:** Other employment-based plans include health plans sponsored by unions and health plans offered by trade or business associations. Union-sponsored health plans are the result of a collective bargaining process with the companies that employ the union members. Health care benefits are one of the most important components of the collective bargaining agreement. If the union has sufficient membership, they may elect to self insure, however, they also may be fully insured. Similarly, some trade or business associations offer health plans to their members' employees. In 2019, only 1.9 percent of workers in the private sector were enrolled in a union-offered plan and 3.8 percent were enrolled in a plan sponsored by a trade or business association.[70] Named Plaintiff and proposed TPP class member MADA provides benefits funded by employers (dealerships) that participate in the trust.[71] The variety of plans falling under this categorization would be members of the proposed TPP class.

2. Retiree Coverage

49. An optional prescription drug benefit, known as Part D, was added to Medicare in 2006 and is funded by a combination of federal subsidies and enrollee premiums. As shown in **Table 1** above, [redacted]

50. The Medicare Part D benefit can be provided as a standalone drug plan ("PDP") or as part of a Medicare Advantage ("MA-PD") offering.[72] PDP and MA-PD plan sponsors prepare and submit annual bids to the Centers for Medicare & Medicaid Services ("CMS") which estimate the expected total prescription drug spending among covered beneficiaries. The federal government provides plan sponsors with two payments: (1) a

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70 Medical Expenditure Panel Survey, "Table II.B.2.d Percent of private-sector employees that are enrolled in plans offered through a union (multi-employer health plan (MEHP)) or a trade or business association (AHP)) or neither by selected characteristics: United States, 2019," available at https://meps.ahrq.gov/data_stats/quick_tables_results.jsp?component=2&subcomponent=2&year=-1&tableSeries=2&tableSubSeries=&searchText=union&searchMethod=3&Action=Search.

71 Deposition of Thomas Brown, MADA, May 28, 2021, p. 80:12-22.

72 Centers for Medicare & Medicaid Services ("CMS"), "How Medicare Prescription Drug Coverage Works with a Medicare Advantage Plan or Medicare Cost Plan," May 2018, available at https://www medicare.gov/Pubs/pdf/11135-prescription-drug-coverage-with-ma-mcp.pdf.

prospective monthly direct subsidy based on the national average bid for Part D benefits, and (2) a reinsurance amount to reimburse plans for drug spending above a consumers' annual out-of-pocket threshold; the reinsurance amounts are reconciled between the federal government and the individual plan at the end of each benefit year.[73] Together, the direct subsidy and reinsurance amount from the federal government is expected to cover 74.5 percent of the plan sponsor's costs for Part D benefits, and the remainder is expected to be covered by consumers' premiums.[74] The payments provided from the federal government to plan sponsors are independent of spending on a specific drug, which make isolating the portion of the net costs actually incurred by this type of TPP for the at-issue VCDs—such as on the claims assigned to Named Plaintiff MSP—exceedingly difficult, as discussed in **Section III.D**.

51. In addition to the direct subsidy and reinsurance to the TPP, the federal government is also involved in payments for specific prescription claims, depending on an individual's phase of coverage based on the Medicare Part D standard benefit design. The Medicare Part D standard benefit design has included the same general structure since its inception, although some of the details have evolved over time. The standard benefit design in 2018 included[75]:

a. a deductible period (up to $405 in total drug spending) where the beneficiary is responsible for 100 percent of the drug cost;

b. an initial coverage period ($405.01 to $3,750 in total drug spending) where the beneficiary pays 25 percent of the drug cost;

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73 MedPac, "Status Report on the Medicare Prescription Drug Program (Part D)," March 2017, available at https://www medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar17_medpac_ch14.pdf ("MedPac 2017 Report on Medicare Part D"), pp. 412-413.

74 MedPac 2017 Report on Medicare Part D, p. 413.

75 Kaiser Family Foundation, "The Medicare Part D Prescription Drug Benefit," October 2017, available at https://files.kff.org/attachment/Fact-Sheet-The-Medicare-Part-D-Prescription-Drug-Benefit, p. 2.

c. a coverage gap (otherwise known as the "donut hole") where the beneficiary is responsible for 35 percent of the cost of brand-name drugs and 44 percent of the cost of generic drugs;[76] and

d. a catastrophic coverage phase (once the patient exceeds $5,000 in out-of-pocket spending) where the beneficiary pays 5 percent of the cost of the prescription, the plan sponsor pays 15 percent, and the federal government pays for the remainder of the cost. The total drug spending necessary to reach the catastrophic threshold was approximately $8,400 in 2018 and generally depends on the mix of branded and generic products used while the patient is in the coverage gap.

52. Both PDPs and MA-PD plans can create their own benefit designs as long as they are actuarially equivalent to the "standard" design.[77] This can result in a variety of benefit designs and differences in cost-sharing arrangements across Part D plans, and within plans over time depending on the characteristics of beneficiaries and their plan design.

3. Other Payor Types

53. In addition to employer-sponsored health plans, union/trade association health plans, and retiree coverage, there are several other types of government and third-party payors for pharmacy benefits.

54. Medicaid provides a wide range of health care services for low-income individuals through private managed care organizations ("MCOs") that contract with states and through a fee-for-service ("FFS") system.[78] Over two-thirds of Medicaid beneficiaries are enrolled in managed care plans, most of which include pharmacy benefit offerings.[79]

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[76] The degree of coverage within the "coverage gap" has increased over time, and as of 2019 there was no coverage gap. Cubanski, Juliette et al., "Closing the Medicare Part D Coverage Gap: Trends, Recent Changes, and What's Ahead," Kaiser Family Foundation, August 2018, available at https://files.kff.org/attachment/Data-Note-Closing-the-Medicare-Part-D-Coverage-Gap-Trends-Recent-Changes-and-Whats-Ahead, pp. 1, 5.

[77] *See* Hoadley, Jack et al., "Medicare Part D at Ten Years: The 2015 Marketplace and Key Trends, 2006-2015," Kaiser Family Foundation, October 2015, available at https://files.kff.org/attachment/report-medicare-part-d-at-ten-years-the-2015-marketplace-and-key-trends-2006-2015, p. 6.

[78] Rudowitz, Robin, et al., "10 Things to Know about Medicaid: Setting the Facts Straight," Kaiser Family Foundation, March 6, 2019, available at https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-setting-the-facts-straight/.

[79] Rudowitz, Robin, et al., "10 Things to Know about Medicaid: Setting the Facts Straight," Kaiser Family Foundation, March 6, 2019, available at https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-

Under Medicaid managed care, states provide MCOs with an upfront monthly payment for expected costs of services, administrative costs, and profits.[80] In contrast, under FFS, the state pays healthcare providers for the covered services used by individuals.[81] In 2020, the total spending for Medicaid managed care was $359.6 billion across 50 states and six territories.[82] New York alone spent almost $8 billion and Pennsylvania almost $6 billion. In addition to the state's monthly payments to MCOs, manufacturers can enter into rebate agreements with the federal government and provide supplemental rebates for states.[83]

55. As part of the ACA, health insurance exchanges were launched in late 2013.[84] Individuals and small businesses may purchase health insurance plans offered by private insurers through these exchanges. Consumers under a certain income threshold may be eligible for subsidies to reduce their cost of coverage, provided in the form of premium tax credits or cost-sharing reductions, in which the insurer offers reduced deductibles and out-of-pocket limits in exchange for a further government subsidy.[85]

56. Uninsured consumers may pay for their prescriptions using discount card or coupon programs, such as GoodRx. GoodRx does not bear the cost for any prescription drugs, but helps consumers find lower prices and discounts.[86] Nevertheless, discount cards

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medicaid-setting-the-facts-straight/. Four states (Missouri, Tennessee, West Virginia, and Wisconsin) do not offer pharmacy benefits in their MCO contracts. *See* National Conference of State Legislatures, "Medicaid Prescription Drug Laws and Strategies," August 27, 2021, available at https://www ncsl.org/research/health/medicaid-pharmaceutical-laws-and-policies.aspx.

80 Dolan, Rachel and Marina Tian, "Management and Delivery of the Medicaid Pharmacy Benefit," Kaiser Family Foundation, December 6, 2019, available at https://www kff.org/medicaid/issue-brief/management-and-delivery-of-the-medicaid-pharmacy-benefit/; Hinton, Elizabeth and MaryBeth Musumeci, "Medicaid Managed Care Rates and Flexibilities: State Options to Respond to COVID-19 Pandemic," Kaiser Family Foundation, September 9, 2020, available at https://www.kff.org/medicaid/issue-brief/medicaid-managed-care-rates-and-flexibilities-state-options-to-respond-to-covid-19-pandemic/.

81 MACPAC, "Provider Payment and Delivery Systems," available at https://www macpac.gov/medicaid-101/provider-payment-and-delivery-systems/.

82 Allen, Kristin, "Medicaid Managed Care Spending in 2020," Health Management, February 25, 2021, available at https://www healthmanagement.com/blog/medicaid-managed-care-spending-in-2020/.

83 Dolan, Rachel, "Understanding the Medicaid Prescription Drug Rebate Program," Kaiser Family Foundation, November 12, 2019, available at https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/.

84 Forsberg, Vanessa C., "Overview of Health Insurance Exchanges," Congressional Research Service, February 16, 2021, available at https://sgp.fas.org/crs/misc/R44065.pdf, at pp. 1-2.

85 Forsberg, Vanessa C., "Overview of Health Insurance Exchanges," Congressional Research Service, February 16, 2021, available at https://sgp.fas.org/crs/misc/R44065.pdf, at pp. 14-15.

86 GoodRx, "How GoodRx Works," available at goodrx.com/how-goodrx-works.

are sometimes classified as "TPPs" in various industry data sources.[87] Therefore, the proposed TPP class definition specific to this litigation is not necessarily consistent with how a "TPP" is defined in the industry. A careful review of the data and the entities listed within them is required to determine the relevant TPP class members, as I discuss in **Section IV.A**.

57. As illustrated in this subsection, there are many different types of payors involved in providing health benefits, including parties that do not bear the full costs of prescriptions. According to Plaintiffs, the parties who do not bear the cost of VCD prescriptions would not be included in the proposed classes, and therefore must be identified and distinguished from parties who do bear the cost of VCDs. Even if these parties could be ascertained with the data Plaintiffs propose using, determining the share of costs borne only by proposed class members is even more complex and varies across payors, depending on the specific benefit designs and individual characteristics of a given plan's beneficiaries.

C. Pharmacy Benefit Programs Offered by Third-Party Payors Differ Along Numerous Dimensions

58. There are a variety of options available to TPPs when designing a pharmacy benefit program, which results in wide variation in the prices paid by TPPs and consumers for a prescription. In this subsection, I describe the numerous options available to entities when designing their pharmacy benefit programs and provide examples of the ways in which pharmacy benefit plans impact access to, and the price paid by, a TPP and/or consumer for a given drug.

1. Choice of PBM

59. Most private TPPs that offer a pharmacy benefit to their employees or beneficiaries do so through a PBM. PBMs assist TPPs in designing their pharmacy benefit programs, offer them multiple options to choose from, and charge an associated administrative fee for managing the pharmacy benefit. TPPs have a large number of options when choosing a PBM. Each PBM offers a different combination of experience, market

[87] *See, e.g.,* Backup Production to Conti Declaration, file "IQVIA Plan Model Type Listing.xlsx"; Deposition of Catherine Stimmel, Director of U.S. Pharmacy Assurance and Patient Safety at Walgreens, September 20, 2021 ("Stimmel Deposition"), p. 159:3-11.

segment focus, financial terms, rebate and performance guarantees,[88] and range and quality of services. For example, [redacted].[89] Other PBMs seek to promote their tailored solutions: for example, Pharmacy Benefit Dimensions is a PBM serving over 4,000 employer groups that emphasizes its partnership with clients through a dedicated account manager and client support team,[90] while myMatrixx is an ESI company specifically focused on workers compensation.[91]

60. The contractual relationships between TPPs and PBMs are individualized and described in a pharmacy benefit management services agreement. Pharmacy benefit management can be contracted together with a medical benefit, or it can be "carved out" and contracted directly with a PBM.[92] In 2017, the Pharmacy Benefit Management Institute ("PBMI") found that 46 percent of 238 surveyed employers carved their drug benefit out from their medical benefit.[93] Out of the same set of 238 employers, 43 percent contracted directly with a PBM to manage their pharmacy benefits, while 51 percent contracted with a third-party administrator.[94] As I discuss in **Section IV.A**, these contractual relationships and the presence of intermediaries complicate the identification of the relevant payer in any transaction involving TPAs or ASOs.

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88 Performance guarantees are a list of service expectations offered by a PBM. PBM contracts will specify the details of each guarantee, including the dollar amount at risk if the PBM fails to meet the standard of each guarantee. Performance guarantees vary by PBM. Callahan, Gregory O. and Angela Reed, "PBM Best Practices Series: Performance Guarantees," Milliman, September 2020, available at https://us milliman.com/-/media/milliman/pdfs/2020-articles/articles/11-6-20-pbm-best-practice-series-v1.ashx.

89 *See, e.g.,* MSP-HFHC-042210-2279 at 2237-2247.

90 Pharmacy Benefit Dimensions, "About," available at https://www.pbdrx.com/about; Pharmacy Benefit Dimensions, "When It Comes to PBMs, Bigger Does Not Mean Better," available at https://www.pbdrx.com/about/pbm-resources/case-studies/customization.

91 MyMatrixx, "PBM Solutions," available at https://www mymatrixx.com/pbm-solutions.

92 *See, e.g.*, Anderson, Brain N. and Angela Reed, "PBM Best Practices Series: Carve-in vs carve-out programs," Milliman, December 2019, available at https://us milliman.com/-/media/milliman/pdfs/articles/best-practices-pharmacy-benefits-carve-in-carve-out.ashx, p 1.

93 Pharmacy Benefit Management Institute, "2017 Trends in Drug Benefit Design," 2017, Figure 10.

94 Pharmacy Benefit Management Institute, "2017 Trends in Drug Benefit Design," 2017, Figure 11.

61. Each contract between a PBM and a TPP is different, highlighting the unique factors that determine the price a TPP pays. Each contract defines different fees, costs, rebates, and reimbursements depending on the type of drug (e.g., brand vs. generic) and pharmacy (e.g., in-network vs. out of network), PBM services, and performance guarantees.[95] Industry analysts recognize that PBMs have "different models,"[96] which is consistent with my own industry knowledge and experience.

62. In the following subsections, I further discuss various dimensions of the pharmacy benefit program design.

2. Formulary Management

63. A formulary is "a continually updated list of prescription drugs approved for reimbursement by the PBM's payer client,"[97] and "[t]he primary purpose of the formulary is to encourage the use of safe, effective and most affordable medications."[98] TPPs work with their PBM to implement their pharmacy benefit and determine (1) whether to cover specific drugs or classes of drugs, such as lifestyle drugs (*i.e.*, non life-threatening conditions), based on their members' needs, (2) how costs will be shared between patients and the TPP, and (3) to what extent to implement utilization management tools and disease management programs to limit or encourage beneficiaries' access to specific drugs.[99]

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95 *See, e.g.,* MSP-HFHC-042210-2279; MSP-EMBLEM-041394-1471; MSP-EMBLEM-000713-0808; MSP-EMBLEM-033741-3880.

96 Werble, Cole, "Pharmacy Benefits Managers," Health Affairs, September 14, 2017, available at https://www healthaffairs.org/do/10.1377/hpb20171409.000178/full/.

97 Pharmaceutical Care Management Association, "What's a formulary?" 2021, available at https://www.pcmanet.org/pcma-cardstack/what-is-a-formulary/. *See also* Chase, Kathy A., "Medication Management" in *Introduction to Hospital and Health-System Pharmacy Practice*, 2010, available at https://www.ashp.org/-/media/store%20files/p2371-sample-chapter-4.pdf, p. 59.

98 Academy of Managed Care Pharmacy, "Formulary Management," July 18, 2019, available at https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/formulary-management.

99 *See, e.g.*, Seeley, Elizabeth, and Aaron S. Kesselheim, "Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead," Issue Brief, March 2019, available at https://www.commonwealthfund.org/publications/issue-briefs/2019/mar/pharmacy-benefit-managers-practices-controversies-what-lies-ahead, Exhibit 1, p. 2; Bihari, Michael, "Understanding Your Health Plan Drug Formulary," June 24, 2021, Verywell Health, available at https://www.verywellhealth.com/understanding-your-health-plan-drug-formulary-1738897.

64. There are three general types of formulary designs that PBMs offer to TPPs:[100]

a. Plans with **open** formularies typically cover all drugs, with some TPP-specified exclusions or restrictions;

b. Plans with restricted or **closed** formularies cover only drugs listed on the formulary. However, there are exception processes for beneficiaries to obtain non-formulary drugs; and

c. In between these two types of formularies, there are a variety of strategies that plans can implement to "encourage" the use of drugs in preferred tiers by patients, pharmacies, and physicians. These strategies can include differential copayments and other financial incentives. These types of formularies are typically referred to as **managed** formularies.

65. Formulary design is typically entrusted to an independent P&T committee that assesses the clinical attributes of a drug, including the safety, efficacy, and substitutability of the drug with other available drugs in the same therapeutic category.[101] If the P&T committee finds that a new drug is superior to others already on the formulary, the drug will usually be added. If there are multiple drugs with similar clinical characteristics, the PBM may decide to limit the number of drugs included in a formulary—a decision that is usually guided by a product's net cost, which in turn depends on multiple factors including the rebates and discounts it has negotiated. For example, [redacted]

[100] Express Scripts, "White Paper: Formulary Development at Express Scripts," December 2020, available at https://express-scripts.com/aboutus/formularyinformation/development/formularyDevelopment.pdf, p. 4; Deposition of Tiffanie Mrakovich, Director of Pharmacy at SummaCare, July 22, 2021 ("July Mrakovich Deposition"), pp. 52:16-53:21, 56:21-57:16.

[101] American Society of Health-System Pharmacists, "ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System," *American Journal of Health-System Pharmacy*, Vol. 78, 2021, pp. 907-918; Academy of Managed Care Pharmacy, "Formulary Management," November 2009, available at https://www.amcp.org/sites/default/files/2019-03/Formulary%20Management.pdf, pp. 2-3.

[redacted][102] An ESI white paper discussing formulary development describes a similar process. The P&T committee reviews medications "from a purely clinical perspective," while the VAC "considers the value of drugs by evaluating the net cost, market share, and drug utilization trends of clinically similar medications."[103]

66. In addition, the P&T committee may track patent expiry of products and identify generic alternatives to the brand drug that are likely to be introduced in the market. At the point that a branded drug loses exclusivity, from my experience in the industry, if multiple manufacturers enter the market with a generic alternative, the generics are typically added to formularies as tier 1 products with varying but relatively lower copay requirements for beneficiaries to incentivize switching from the brand to the lower cost generic alternative.

67. PBMs may maintain multiple formularies, with different criteria for each one. Formulary design can vary across lines of business. For example, [redacted].[104] Furthermore, formulary design can vary within a single line of business for a TPP. For example, [redacted][105]

68. A TPP may choose to adopt a PBM's standard formulary with no changes, use a PBM's standard formulary as the basis for their own custom formularies,[106] or adopt a formulary developed by a different entity, such as a health plan or TPA. In 2017, PBMI's

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102 ANTM_MADA_SUBP_00002229-2258 at 2243.

103 Express Scripts, "White Paper: Formulary Development at Express Scripts," December 2020, available at https://express-scripts.com/aboutus/formularyinformation/development/formularyDevelopment.pdf, p. 2.

104 Deposition of Margaret Finn, EmblemHealth and ConnectiCare, July 30, 2021, ("Finn Deposition, EmblemHealth and ConnectiCare") p. 120:7-12.

105 Finn Deposition, EmblemHealth and ConnectiCare, pp. 129:20-130:25.

106 Express Scripts, "White Paper: Formulary Development at Express Scripts," December 2020, available at https://corporate-site-labs-prod.s3.us-east-2.amazonaws.com/2020-12/Formulary%20Development%20December%202020.pdf, p. 4.

survey results indicate that 73 percent of employers adopted the PBM's formulary, while 23 percent of employers customized their formulary and 4 percent used a formulary developed by a health plan or TPA.[107] A combination of formularies is also possible within a single TPP. For example, [redacted][109] This is an example of how TPPs may incorporate consumer preferences into their formulary designs, and reflects value that TPPs derive from their formulary offerings in being able to attract and retain members.

69. The variations in formulary options offered by PBMs result in great variation in the prices paid by TPPs for medications. PBMs maintain multiple formularies and TPPs sometimes customize them to suit their own preferences. The TPP decision of whether to provide an open, managed, or closed formulary directly impacts the terms under which drugs are available to beneficiaries and may impact how drugs are prescribed. Additional decisions related to cost sharing and utilization management, described below, further impact prescription choices and prices paid by a TPP and/or consumer.

3. Retail Pharmacy Networks

70. PBMs offer TPPs access to multiple pharmacy networks. PBMs create networks of pharmacies by negotiating prescription prices (discount rates) and dispensing fees with pharmacies.[110] PBMs negotiate multiple pharmacy networks with different negotiated prices. Each PBM negotiates and renegotiates pharmacy networks on a continual basis to lower the costs to their TPP customers.

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107 Pharmacy Benefit Management Institute, "2017 Trends in Drug Benefit Design," 2017, Figure 23.

108 Finn Deposition, EmblemHealth and ConnectiCare, p. 91:17-23.

109 July Mrakovich Deposition, pp. 53:16-25, 56:12.

110 Werble, Cole, "Prescription Drug Pricing: Pharmacy Benefit Managers," Health Affairs Health Policy Brief Series, September 14, 2017, available at https://www healthaffairs.org/do/10.1377/hpb20171409.000178/listitem/healthpolicybrief_178.pdf.

71. Pharmacy networks can be open to all pharmacies willing to accept the PBM's terms and conditions or can be narrow and restrictive.[111] For example, a narrow network may only include one major chain of pharmacies. Narrow networks can result in higher negotiated pharmacy discounts, and therefore lower prices to the TPP. For example, [redacted][112] [redacted]

72. TPPs select the specific PBM pharmacy network to offer in their pharmacy benefit. The network offered to a TPP may be a hybrid network with a portion of the network open and a portion restricted based on the reasons above. Patient cost-sharing amounts vary between preferred pharmacies and standard (non-preferred) pharmacies.[113]

4. Mail-Order Pharmacy Services

73. Most PBMs offer mail-order pharmacy services to TPPs. TPPs can establish different benefit designs to financially incentivize (or require) patients with chronic conditions to utilize these mail-order services.[114] Mail-order pharmacies are particularly cost-effective for chronic conditions because they offer lower prices as compared to retail pharmacies.[115] For example, [redacted][116] PBMs also created a separate type of pharmacy network, now known as Retail 90 Pharmacy networks, that

111 Express Scripts, "Ask the Expert: What's A Good Pharmacy Network Strategy?" available at https://www.express-scripts.com/corporate/articles/ask-expert-whats-good-pharmacy-network-strategy.

112 ANTM_MADA_SUBP_00002229-2258 at 2257-2258.

113 Finn Deposition, EmblemHealth and ConnectiCare, pp. 140:21-142:1.

114 *See* Pharmaceutical Care Management Association, "PBM Mail-Service Pharmacies," available at https://www.pcmanet.org/pbm-mail-service-pharmacies/.

115 Pharmaceutical Care Management Association, "PBM Mail-Service Pharmacies," available at https://www.pcmanet.org/pbm-mail-service-pharmacies/.

116 ANTM_MADA_SUBP_00002229-2258 at 2257-2258.

enables retail pharmacies to fill up to a 90-day supply of medication for patients. The reimbursement rates for Retail 90 pharmacy networks are similar to mail service rates: for example, [redacted].[117] It is the TPP's decision whether to offer a Retail 90 network in their pharmacy benefit plan.

74. TPPs vary in their preferences for providing access to mail-order pharmacies for their beneficiaries, which results in differences in benefits offered. For example, a 2017 PBMI survey found that 17 percent of employers with plans covering mail order fills required the use of the mail-order pharmacy for maintenance medications,[118] while 11 percent of employers required the use of the mail-order pharmacy only for select maintenance medications.[119]

75. Anti-hypertensive treatments such as ARBs (valsartan's class of medication) and angiotensin-converting enzyme inhibitors ("ACE-Is"), an alternative first-line treatment for hypertension,[120] are typically considered maintenance medications, and therefore are well-suited for mail-order pharmacy services. For example, three recent publicly available maintenance drug lists from CVS Caremark,[121] CareFirst,[122] and Kroger[123] list anti-hypertensive drugs as maintenance drugs. Thus, the details of the mail-order benefit offered by a TPP and managed by a PBM may affect the total prices paid for a generic VCD, as well as the share of costs, if any, paid by different entities.

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117 ANTM_MADA_SUBP_00002229-2258 at 2257-2558.

118 Maintenance medications are prescription drugs that are used to treat chronic or long-term conditions. CVS Caremark, "CVS Caremark Maintenance Drug List," July 1, 2017, available at https://www.osc.ct.gov/empret/healthin/2011hcplan/MaintenanceDrugListJuly2011.pdf.

119 Pharmacy Benefit Management Institute, "2017 Trends in Drug Benefit Design," 2017, Figure 34.

120 Jimenez, Darcy, "Hypertension: study suggests ARBs should be used before ACE inhibitors," Pharmaceutical Technology, July 28, 2021 (last updated December 9, 2021), available at https://www.pharmaceutical-technology.com/news/hypertension-study-arbs-ace-inhibitors/.

121 CVS Caremark, "CVS Caremark Maintenance Drug List (Effective as of 12/15/2021)," available at https://www.caremark.com/portal/asset/CVS_Caremark_Maint_DrugList.pdf.

122 CareFirst, "Maintenance Drug List (Effective October 2020)," available at https://member.carefirst.com/carefirst-resources/pdf/maintenance-drug-list-sum2723.pdf.

123 Kroger Prescription Plans, "Adhere 90: Maintenance Drug List (Effective January 1, 2021)," available at https://www kpp-rx.com/documents/KPP%20Adhere%2090%20Drug%20List.pdf.

5. Benefit Design and Cost Sharing

76. TPPs combine their choice of formulary, plan design decisions, utilization management edits, and cost-sharing strategies with beneficiaries to finalize their pharmacy benefit. Cost-sharing options include whether beneficiaries pay a fixed amount ("copay") per prescription, or whether they pay a fixed share of the prescription's negotiated price ("coinsurance"). Managed formularies segment drugs into different tiers with different cost-sharing amounts.[124] According to a 2018 survey, more than 90 percent of covered workers had a plan with tiered cost sharing for prescription drugs (a managed formulary or a preferred drug list).[125] Among the plans surveyed, there was a broad variability of the number of tiers, average copayments, and coinsurance rates.[126] The combinations of formulary and cost sharing create a wide variety of possible pharmacy benefit designs.

77. There are many components to drug formulary design, which may vary by PBM/plan based on their utilization management strategies. Important components of formulary design include drug tiers (e.g., preferred generics, non-preferred generics, preferred brands, non-preferred brands, and specialty drugs), as well as clinical edits such as prior authorization, step edits, and quantity limits. For example, [redacted].[128]

78. TPPs may require their beneficiaries to meet deductibles before covering a portion of their pharmacy benefit. The deductible may include expenditures made on the

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124 Werble, Cole, "Formularies," Health Affairs Health Policy Brief, September 14, 2017, at p.1, available at https://www healthaffairs.org/do/10.1377/hpb20171409.000177/full/hpb_2017_09_14_formularies.pdf.

125 Kaiser Family Foundation, "2018 Employer Health Benefits Survey," October 3, 2018, available at https://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018, pp. 153-154.

126 Kaiser Family Foundation, "2018 Employer Health Benefits Survey," October 3, 2018, available at https://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018, Section 9.

127 July Mrakovich Deposition, SummaCare, p. 67:9-16.

128 July Mrakovich Deposition, SummaCare, pp. 69:22-70:17.

pharmacy benefit only or may also include expenditures made on the medical benefit. Deductibles are also applied to either individuals or families, or a combination of both.[129]

79. TPP pharmacy benefits may further have a maximum out of pocket ("MOOP") amount, at which point full coverage kicks in and the TPP pays for 100 percent of the cost of prescription drugs. In 2020, most covered workers were enrolled in health plans with a MOOP for their health benefits, which may also apply to prescription drug coverage; the same study noted that "[m]any plans have complex out-of-pocket structures, which makes it difficult to accurately collect information on this element of plan design."[130] These decisions on what coverage and beneficiary cost-sharing structure to offer directly impact the cost of the pharmacy program to the TPP, as well as the amounts that TPPs pay for their beneficiaries' prescriptions.

80. Medicare Part D plans have an additional layer of complication. As discussed in **Section III.B**, the standard Part D benefit design includes a gap in coverage during which plan sponsors pay only a fraction of the cost of generic drugs. This fraction varied from 14 percent in 2012 to 56 percent in 2018; roughly 25 percent of Part D enrollees reached the coverage gap during the class period.[131] For patients in the coverage gap, the percentage of generic drug spending covered by plan sponsors increased from 7 percent in 2011 to 75 percent in 2020.[132]

81. The various dimensions described throughout this section demonstrate that TPPs' pharmacy benefit programs are individualized and often result in different coverage for the same drug. TPPs often offer multiple plans to beneficiaries that contain different

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129 In 2017, 11 percent of employers surveyed by PBMI reported having a separate annual deductible for prescription drug benefits, a decrease from 2016, when this share was 13 percent. Pharmacy Benefit Management Institute, "2017 Trends in Drug Benefit Design," 2017, Figure 28.

130 Kaiser Family Foundation, "2020 Employer Health Benefits Survey," October 8, 2020, available at https://www kff.org/health-costs/report/2020-employer-health-benefits-survey/, p. 127.

131 Cubanski, Juliette, et al., "Closing the Medicare Part D Coverage Gap: Trends, Recent Changes, and What's Ahead," Kaiser Family Foundation, August 21, 2018, available at https://www kff.org/medicare/issue-brief/closing-the-medicare-part-d-coverage-gap-trends-recent-changes-and-whats-ahead/. CMS, "The Affordable Care Act – A Stronger Medicare Program in 2012," February 7, 2013, available at https://www.cms.gov/newsroom/press-releases/affordable-care-act-stronger-medicare-program-2012.

132 Kaiser Family Foundation, "Explaining Health Care Reform: Key Changes to the Medicare Part D Drug Benefit Coverage Gap," March 2010, available at https://www.kff.org/wp-content/uploads/2013/01/8059.pdf, Exhibit 4.

cost-sharing arrangements, resulting in different prices paid by proposed class members. For example, as shown below in **Table 2**, as of 2021, there were several different coverage options for the deductible and initial coverage period across MSP assignors' and MADA health plans. If MADA's formulary included valsartan on tier 1 [redacted][133] a MADA member would have paid [redacted] for their medication, while MADA would have paid [redacted], as negotiated between [redacted][134] In contrast, a SummaCare commercial patient would have paid $0 for valsartan on tier 1 (as it was in 2021),[135] [redacted]

Table 2
Coverage Options Across Health Plans, 2021 or 2022

TPP and Plan	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6
Commercial Plans						
SummaCare HMO Silver 5000 40[136]	$0 copay	$15 copay	$25 copay	$2000 ded.; 40% coins.	$2000 ded.; 50% coins.	$2000 ded.; 50% coins.
ConnectiCare Choice Silver Standard POS[137]	$10 copay	$250 ded.; $45 copay	$250 ded.; $70 copay	$250 ded.; 20% coins. up to $200 max	N/A	N/A

[redacted]

133 ANTM_MADA_SUBP_00000417-0507 at 0443.

134 ANTM_MADA_SUBP_00002229-2258 at 2257-2258.

135 SummaCare, "SummaCare 2021 Comprehensive Formulary (Effective 12/1/2021)," available at https://www.summacare.com/-/media/project/summacare/website/document-library/formulary-documents/2021-rx-commercial-formulary.pdf?la=en, p. 91.

136 SummaCare, "SummaCare HMO Silver 5000 40 Schedule of Benefits," available at https://www.summacare.com/-/media/project/summacare/website/document-library/sobs/ifp/2022/2022-sob-summacare-silver-5000-40-ehb-only.pdf?la=en. Copays and coinsurance are under the 30-day supply of preferred retail pharmacy.

137 ConnectiCare, "Individual Market Choice Silver Standard POS Benefit Summary," available at https://www.connecticare.com/content/dam/connecticare/pdfs/members/plans/access/summary/Choice-Silver-Standard-POS-Summary-2021.pdf. Copays and coinsurance are under the 30-day supply of preferred retail pharmacy.

138 ANTM_MADA_SUBP_00000254-0257 at 0256. [redacted]

TPP and Plan	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6
Medicare Advantage Plans						
SummaCare Medicare Ruby HMO[139]	$0 copay	$8 copay	$44 copay	$100 copay	33% coins.	N/A
SummaCare Medicare Topaz HMO[140]	$0 copay	$10 copay	$150 ded.; $47 copay	$150 ded.; $100 copay	30% coins.	N/A
EmblemHealth VIP Rx Saver HMO[141]	$2 copay	$15 copay	$42 copay	$395 ded.; $95 copay	$395 ded.; 25% coins.	N/A
EmblemHealth VIP Go HMO-POS[142]	$2 copay	$15 copay	$250 ded., $42 copay	$250 ded.; $95 copay	$250 ded.; 28% coins.	N/A
ConnectiCare Choice Part B Saver HMO[143]	$2 copay	$445 ded.; $10 copay	$445 ded.; $42 copay	$445 ded.; $95 copay	$445 ded.; 25% coins.	N/A
ConnectiCare Flex Plan 1 HMO-POS[144]	$2 copay	$10 copay	$300 ded.; $42 copay	$300 ded.; $95 copay	$300 ded.; 27% coins.	N/A

82. These examples demonstrate that program benefit designs vary substantially.[145] As a result of the many different options available for TPPs to customize their pharmacy benefit programs, there is a wide variation in the prices paid by each TPP

139 SummaCare, "SummaCare Medicare Ruby (HMO)," available at https://www.summacare.com/medicare/plans/2021/ruby-northeast#additional.

140 SummaCare, "SummaCare Medicare Topaz (HMO)," available at https://www.summacare.com/medicare/plans/2021/topaz#additional.

141 EmblemHealth, "2021 Summary of Benefits: EmblemHealth VIP Rx Saver (HMO)," available at https://www.emblemhealth.com/content/dam/emblemhealth/pdfs/plans/medicare/plan-documents/2021/benefit-summaries/tagged_EMB_MB_BRO_51392_2021_SSB_RX-Saver_9-20.pdf, p. V-8.

142 EmblemHealth, "2021 Summary of Benefits: EmblemHealth VIP GO (HMO-POS)," available at https://www.emblemhealth.com/content/dam/emblemhealth/pdfs/plans/medicare/plan-documents/2021/benefit-summaries/tagged_EMB_MB_BRO_51392_2021_SSB_VIPGo_9-20.pdf, p. VII-9.

143 ConnectiCare, "ConnectiCare Choice Part B Saver (HMO)," available at https://www.connecticare.com/content/dam/connecticare/pdfs/medicare/2021-welcome-kits/Choice%20Part%20B%20Saver%20NO%20Optional%20Dental.pdf. Copays and coinsurance are under the 30-day supply of preferred retail pharmacy.

144 ConnectiCare, "ConnectiCare Flex Plan 1 (HMO-POS)," available at https://www.connecticare.com/content/dam/connecticare/pdfs/medicare/2021-welcome-kits/Flex%20Plan%201%20NO%20Optional%20Dental.pdf. Copays and coinsurance are under the 30-day supply of preferred retail pharmacy.

145 The deposition of Tiffanie Mrakovich confirmed the different design and payment structure of the SummaCare 2018 Ruby and Topaz plans. *See* Deposition of Tiffanie Mrakovich, Director of Pharmacy at SummaCare, August 31, 2021 ("August Mrakovich Deposition"), pp. 24:12-25:3.

and the consumer for the same generic drug. The price paid for the at-issue VCDs varies due to the formulary and plan benefit design, the pharmacies at which consumers prefer to fill their prescriptions, and consumers' cumulative use of their pharmacy benefit during the plan year. The prices that would have been paid for alternative medications likewise vary for the same reasons.

D. Ascertaining the Class Members Who Bore Prescription Drug Costs, as Opposed to Non-Class Members Like Government Entities or Intermediaries, Is Highly Complex

83. Plaintiffs seek to exclude from the proposed classes a number of parties that paid for at-issue VCDs, such as government payors. Moreover, as recognized by Plaintiffs' expert Ms. Craft, certain parties involved in purchases of at-issue VCDs and PBMs are excluded from the proposed classes because "they are recognized to act only as intermediaries for their TPP clients and not as end-purchasers."[146] Consistent with Ms. Craft's reasoning, any payor that did not actually bear the costs of prescriptions for at-issue VCDs should also be excluded from the proposed classes, such as fully insured TPPs. However, determining the entity (or entities) that actually incurred the cost of a prescription—in whole or in part—is highly complex and requires a significant amount of information specific to the purchase, the pharmacy benefit design, the transactions that occurred prior to the dispensing of the prescription to the consumer, and any reconciliations that occurred subsequently.

84. For example, as explained in **Section III.B**, government payors play an outsized role in the payment for prescriptions of anti-hypertensive drugs, such as VCDs. Medicare PDP and MA-PD plans are directly subsidized by the federal government in several ways, and these subsidies add further complexity to identifying generic VCD costs borne, if any, by proposed consumer and TPP class members, as well as differences in costs associated with generic VCDs compared to alternate anti-hypertensives.

a. First, the prospective payment that each plan receives from the federal government is based on the national average plan's bid, which in turn is based on benefit design, formulary, and anticipated utilization. This prospective payment, combined with

[146] Craft Declaration, at ¶ 13.

the reinsurance, from the federal government is expected to cover 74.5 percent of the plan's costs for Part D benefits.[147] If a Part D plan chooses not to cover generic VCDs, any difference in expected spending on anti-hypertensives would be reflected in the plan's bid and thus paid (or retained) by the federal government.

b. Second, even in the case where plan sponsors may have incorrectly estimated utilization of various types of anti-hypertensives, they are only partially "at-risk" for excess spending. Risk corridors ensure that when plan sponsor costs at the end of the benefit period are 5-10 percent higher than the TPP's bid, the federal government pays half of any amounts above 5 percent; if plan sponsor costs are above 10 percent, the federal government pays 80 percent of the excess and the plan sponsor pays 20 percent.[148] These risk corridor payments are made in aggregate at the end of the benefit period and are not directly attributed to specific products, classes of products, or individual claims. However, they must be accounted for in determining whether and to what extent plan sponsors were made worse off by Defendants' alleged conduct.

c. Third, the catastrophic phase of the Part D benefit design is a form of reinsurance and represents an additional subsidy from the federal government. Between 2010 and 2019, more than 3.6 million Part D enrollees reached the catastrophic threshold.[149] The extent to which plan sponsors and beneficiaries bore the cost of at-issue VCDs or would have borne different costs had they not purchased at-issue VCDs depends on whether the beneficiary exceeded the catastrophic threshold at the time the prescription for the anti-hypertensive was filled.

d. Fourth, certain low-income patients receive extra help from the federal government with beneficiary premiums and cost-sharing obligations.[150] Patients who receive a

147 MedPac 2017 Report on Medicare Part D, p. 413.

148 Kirchhoff, Suzanne M., "Medicare Part D Prescription Drug Benefit," Congressional Research Service, December 18, 2020, available at https://sgp fas.org/crs/misc/R40611.pdf, at Table 7.

149 Cubanski, Juliette et al., "Millions of Medicare Part D Enrollees Have Had Out-of-Pocket Drug Spending Above the Catastrophic Threshold Over Time," Kaiser Family Foundation, July 23, 2021, available at https://www kff.org/medicare/issue-brief/millions-of-medicare-part-d-enrollees-have-had-out-of-pocket-drug-spending-above-the-catastrophic-threshold-over-time/.

150 Kirchhoff, Suzanne M., "Medicare Part D Prescription Drug Benefit," Congressional Research Service, December 18, 2020, available at https://sgp fas.org/crs/misc/R40611.pdf, p. 1.

low-income subsidy ("LIS") face different cost-sharing requirements than non-LIS enrollees, and there is also variation between full-LIS and partial-LIS enrollees.[151] For both groups of LIS enrollees, generic drug cost-sharing is capped by the amount listed in CMS's current annual Call Letter (which specifies the considerations that organizations need to account for in placing their bids to CMS), regardless of formulary tier placement for the specific product. The cost-sharing cap applies to branded products with generic options so long as the pharmacy (rather than physician) chooses to dispense branded product.[152] The lower cost-sharing payments made by LIS enrollees at the pharmacy counter mean that plan sponsors pay a larger share of each prescription. However, the federal government then provides an LIS subsidy to plan sponsors to offset the reduction in beneficiary co-payments.[153] LIS beneficiaries always pay the lesser of plan cost-sharing and CMS statutory cost-sharing.[154] Furthermore, LIS status can be applied retroactively, which then requires the plan to reimburse earlier amounts co-payments paid by the beneficiary.[155] The amount covered by a LIS can vary substantially by factors not readily available in prescription claims data.[156]

e. Finally, the federal government offers the Employer Retiree Drug Subsidy ("RDS") program to employers and unions offering prescription drug coverage to retirement-

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151 CMS, "Medicare Prescription Drug Benefit Manual Chapter 13 - Premium and Cost-Sharing Subsidies for Low-Income Individuals," October 1, 2018, available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-13-Premium-and-Cost-Sharing-Subsidies-for-Low-Income-Individuals-v09-14-2018.pdf ("Medicare Prescription Drug Benefit Manual Chapter 13"), Sections 60.1.2 and 60.3.2.

152 Medicare Prescription Drug Benefit Manual Chapter 13, Section 60.4.1.

153 Medicare Prescription Drug Benefit Manual Chapter 13, Section 10.

154 Medicare Prescription Drug Benefit Manual Chapter 13, Section 60.4.4.

155 Medicare Prescription Drug Benefit Manual Chapter 13, Section 70.

156 The corporate representative for EmblemHealth and ConnectiCare explained that the LIS may vary by "[t]he state of the benefit that the claim is processed in, the low-income status member -- low-income status of the member, existence of other payers on the claim, the types of other payers on the claim. There's a lot of variation." Finn Deposition, EmblemHealth and ConnectiCare, p. 51:10-14.

age beneficiaries. These plans receive additional, aggregated reimbursements for allowable prescription drug expenses.[157, 158]

85. Therefore, determining the cost of an at-issue prescription, if any, borne by a proposed Medicare Part D class member—such as MSP's assignors—requires a significant amount of information on the subsidies paid by government entities that are excluded from the proposed classes. Moreover, determining whether a proposed Medicare Part D class member would have received fewer subsidies from government payors or would have had different costs if they had not purchased at-issue VCDs would be relevant to the assessment of whether the proposed class member suffered economic losses. The information necessary to assess the prescription costs borne by proposed class members versus non-class members is highly individualized and, to the best of my knowledge and experience, there is no common source for this information.

86. Similarly, determining the entity that bore the costs of a prescription requires information about the type of TPP and its contractual relationship with other entities involved in pharmacy transactions. For example, as described above, whereas a self-insured employer would bear a portion of the cost of a prescription purchased by its beneficiary, a fully insured employer pays a premium to an insurance provider that would bear the financial risk associated with that prescription. As such, ascertaining the party that bore the costs of an at-issue prescription would require information on contractual relationships, for which I know of no common source.

87. The characteristics of the industry, the types of payors, the multiple aspects of pharmacy benefit programs that impact the cost-sharing between TPPs and consumers for a prescription drug, and the role of non-class members in the payment for VCDs (e.g., government payors) all work to create a complex pharmaceutical landscape. Plaintiffs' experts have failed to consider these different facets in their opinions, and consequently present opinions based on overly simplified characterizations of the industry. As I discuss in the remainder of my report, the complexity of the pharmaceutical industry leads to a

157 CMS, "Brief Summaries of Medicare & Medicaid, Title XVII and Title XIX of the Social Security Act," November 15, 2019, available at https://www.cms.gov/files/document/brief-summaries-medicare-medicaid-november-15-2019.pdf.

158 CMS, "RDS User Guide," available at https://www.rds.cms.hhs.gov/?q=user-guide/rds-program-overview.

series of overlapping, but not sufficiently complete data sources, that in turn make it very difficult to identify the relevant proposed class members and excluded class members, to accurately determine the amount paid for the at-issue VCDs, or to assess the extent of economic loss without accounting for individual circumstances.

IV. Ms. Craft Fails to Provide a Reliable Methodology for Combining Data Sources to Accurately Identify Proposed Class Members and the Amount Paid for At-Issue Products

88. Ms. Craft was retained by Plaintiffs' counsel "to evaluate whether, given the Proposed Class definitions and the various exclusions applied, it is possible to identify the individual consumers and TPPs who meet their terms."[159] Ms. Craft opines that it is "possible to identify consumer and TPP Class Members using electronic data common to the Proposed Classes."[160] Ms. Craft's assessment of the data sources to identify class members, however, is based on merely identifying disparate sources of data, without any attempt at proposing a methodology to combine these data sources, accurately identify class members, and apply relevant class exclusions. Contrary to Ms. Craft's assertions, the data produced in this matter demonstrate that individualized inquiry is required to identify class members and apply class exclusions, particularly in this case where there are numerous sub-classes and complex class exclusions. Ms. Craft fails to propose a cohesive methodology for combining the various data sources she claims are available, fails to identify all the information that would be necessary to ascertain the members of each class, and fails to recognize that obtaining and analyzing the necessary data to identify class members is very difficult and burdensome.

A. Data Produced in this Matter Demonstrate that Individualized Inquiry Is Necessary to Identify Class Members

89. Ms. Craft claims that "[o]ne of the defining characteristics of the U.S. pharmaceutical industry is the completeness, redundancy, and detail of its contemporaneously generated transaction data kept and maintained by all parties in the drug supply chain."[161] Ms. Craft relies on industry claims processing transaction formats

159 Craft Declaration, at ¶ 2.

160 Craft Declaration, at ¶ 8.

161 Craft Declaration, at ¶ 16.

published by the National Council for Prescription Drug Program ("NCPDP"), an organization of which I am a member, and the level of regulations in the pharmaceutical industry to claim that "[a]lthough the system sounds complex, the information in fields relevant to this case is intuitive, uncomplicated, and standard."[162] Ms. Craft is incorrect: the system sounds complex because it is complex. Ms. Craft ignores the fact that different organizations in the pharmaceutical supply chain maintain different datasets for their everyday business purposes that do not allow for the identification of the specific class members in this matter. Different data sources are required to identify the various different classes proposed, and the data produced in this matter illustrate the difficulty in combining multiple data sources together, let alone accurately identifying the proposed class members and exclusions without individualized research.

1. TPP Class Members Cannot Be Reliably Identified in an Administratively Feasible Manner

90. Ms. Craft's declaration primarily focuses on "three institutional sources of electronic, transaction-specific data that identify payors associated with a prescription drug purchase": data maintained by pharmacies, PBMs, and TPPs.[163] However, Ms. Craft both overstates the availability of data to identify members of the various proposed TPP sub-classes and oversimplifies the complex contractual relationships in the flow of pharmacy benefit payments that I discussed in **Section III.A**. Even if the data Ms. Craft proposes to use were as easily available as she contends, the contractual arrangements between PBMs, TPPs, and intermediaries, such as TPAs or ASOs,[164] will make it particularly difficult to accurately identify the ultimate payor for a given prescription claim, which would be the TPP class member. Contrary to Ms. Craft's claims, data produced in this case demonstrate the difficulty in determining the identity of TPP class members.

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162 Craft Declaration, at ¶ 26.

163 Craft Declaration, at ¶ 17.

164 As discussed in **Section III.A**, "TPA" refers to a third-party administrator and "ASO" refers to an "Administrative Services Only" organization, whereby a TPP pays claims from its own funds but hires a third party to administer prescription claims and plan benefits.

a) Pharmacy Data Do Not Contain Information on TPPs

91. Pharmacy data are insufficient for identifying the relevant TPP class members. Even though Ms. Craft claims that "testimony from the Retail Pharmacies also confirms that those pharmacies collect and retain information on each pharmaceutical transaction sufficient to identify any TPP that provided payment for the drug,"[165] she later acknowledges that discerning the TPP's identity requires merging the claims information with "additional data PBMs maintain about their clients."[166]

92. The Walgreens testimony that Ms. Craft cites is vague: it simply states [redacted] as discussed in **Section III.B**, discount card programs are not payors and would be excluded from the class under Plaintiffs' proposed definitions. Furthermore, Ms. Craft also excludes discount card programs from her estimate of TPPs in this matter.[168] None of the other pharmacy datasets on which Ms. Craft relies contain information related to TPPs or payment types.

93. In fact, pharmacies do not necessarily maintain data "sufficient to identify any TPP that provided payment for the drug,"[169] particularly in instances when the pharmacy contracts with PBMs, because the pharmacy does not need information related to the TPP to route the claim for processing and subsequent payment from the PBM. As a result, the pharmacy does not have access to the TPP specific information.

94. Ms. Craft provides an incomplete explanation of the claims adjudication process, stating, that "[e]very time an insured consumer fills a prescription at a pharmacy

165 Craft Declaration, at ¶ 45.

166 Craft Declaration, at ¶ 65.

167 Craft Declaration, at ¶ 45; Stimmel Deposition, Walgreens, p. 159:3-11.

168 Craft Declaration, at ¶ 72; Backup production to this report.

169 Craft Declaration, at ¶ 45.

(whether mail order or brick and mortar), a process known as electronic 'claims adjudication' takes place, typically in a matter of seconds."[170] However, before this electronic claims adjudication process can take place, the pharmacy staff is first required to input relevant information to route the claim in the pharmacy data system.[171] The pharmacist uses information from the insured patient's pharmacy benefit card: in addition to the patient's member information, the pharmacist uses the Issuer Identification Number ("IIN," previously known as Bank Identification Number, or "BIN") and, where applicable, the processor control number ("PCN") and the group ID ("GRP").[172] Contrary to Ms. Craft's claim that these identifiers are associated with the "TPP Identity,"[173] these fields merely ensure that the pharmacy can route the claim to the right entity, e.g., a PBM, for claims processing and payment.

95. The inability of these fields to identify the TPP is illustrated by "payer sheets" that pharmacies receive from PBMs to correctly route claims. An example of such a payer sheet is shown below in **Figure 2**. To route commercial and Medicaid claims for which OptumRx is the PBM, the pharmacy staff would input a BIN of "610494" and a PCN of "9999." The pharmacy staff does not have any additional information related to the underlying plan sponsor, much less whether that health plan is fully insured or self-insured and would therefore meet the proposed TPP class definitions. Instead, from the pharmacy's perspective, OptumRx is the relevant payer, as identified under the "Payer Name," even if OptumRx is not the actual end payer of the claim.

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170 Craft Declaration, at ¶ 18.

171 *See also* Deposition of Patricia Cobb, Anthem Health Plans of Maine d/b/a Anthem Blue Cross Blue Shield, October 21, 2021 ("Cobb Deposition"), pp. 38:17-41:4.

172 NCPDP, "Health Care Identification Card – Implementation Guide," October 2017 ("NCPDP ID Implementation Guide"), p. 9. *See also,* CVS Caremark, "Temporary ID Card," 2019, available at https://www.caremark.com/portal/asset/TRS_tempID.pdf; OptumRx, "2021 Pharmacy Provider Manual," June 24, 2021, available at https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/resources/pdfs/OptumRxPharmacyProviderManual2021-Version3.3.pdf, p. 27.

173 Craft Declaration, Figure 3.

Figure 2
Sample from OptumRx 2021 Payer Sheet for Commercial and Medicaid Clients[174]

Payer Name: OptumRx	Date: 05/01/2021	
Commercial and Medicaid	BIN: 610494	PCN: 9999
Community Health	BIN: 610613	PCN: 2417
ProAct	BIN: 017366	PCN: 9999
FlexScripts/ProAct	BIN: 018141	PCN: 9999
United Healthcare Community Plan of Indiana	BIN: 610494	PCN: 4841
United Healthcare Community Plan of Texas	BIN: 610494	PCN: 4400
United Healthcare Community Plan of Arizona	BIN: 610494	PCN: 4100
United Healthcare Community Plan of Virginia	BIN: 610494	PCN 4900
MedalistRx	BIN: 016580	PCN: <NA>

96. Information on the card issuer may be printed on the member's pharmacy benefit ID,[175] but in my experience, pharmacists do not input this information into the pharmacy system as it is not needed for adjudication. Even if information related to the TPP were readily available on the pharmacy ID card and inputted by pharmacists, the pharmacy does not have access to additional information related to the TPP to accurately and consistently identify the relevant TPP class member.[176]

b) PBM Data Require Individualized Review of Intermediaries' Relationships with TPPs

97. Although PBMs maintain information that identifies *clients* they bill for their services, identifying the relevant *TPP class member* still requires individualized research due to the presence of intermediaries, such as TPAs and insurers providing ASO services. In contrast to Ms. Craft's claim (citing no data or other source) that "[t]he vast majority of TPPs contract directly with PBMs to administer their prescription drug programs,"[177] in reality, many TPPs use intermediaries. As mentioned in **Section III.C**, PBMI found that 51 percent of employers surveyed in 2017 contracted with a PBM through

174 OptumRx, "NCPDP Version D.0 Payer Sheet, Commercial and Medicaid," May 1, 2021, available at https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/resources/payer-sheets/2021OptumRxCommercial-Medicaid.pdf.

175 *See, e.g.,* CVS Caremark, "Temporary ID Card," 2019; OptumRx, "2021 Pharmacy Provider Manual," June 24, 2021, at p. 27.

176 Although the NCPDP implementation guide for ID cards mentions a unique card issuer ID that could be traced back to self-funded or fully-insured plans, the use of these IDs are inconsistent and the guidelines note that entities "may not qualify for [a Health Plan Identifier]" or may be "unwilling to obtain an [Other Entity Identifier]." In these cases, a standard NCPDP card identifier of "9151014609" is used on pharmacy cards. *See* NCPDP ID Implementation Guide, p. 12. In my experience, pharmacists do not use the unique issuer ID when submitting claims to the PBM.

177 Craft Declaration, at ¶ 28.

an administrator.[178] This share has remained consistent, with 50 percent of surveyed employers in 2013 reporting that they contracted with a PBM through an administrator.[179] The survey results were reported with more granularity in 2013 and indicate that the use of an intermediary was more common among smaller employers than larger employers.[180]

98. The presence of intermediaries substantially complicates the data exchange between organizations, a process that Ms. Craft overly simplifies in Figure 1 of her declaration. With the presence of intermediaries, the PBM data will at times identify only the intermediary, as Ms. Craft acknowledges.[181] **Figure 3** below is a modified, more accurate version of Ms. Craft's Figure 1 and demonstrates the complexity of contractual arrangements in the industry.

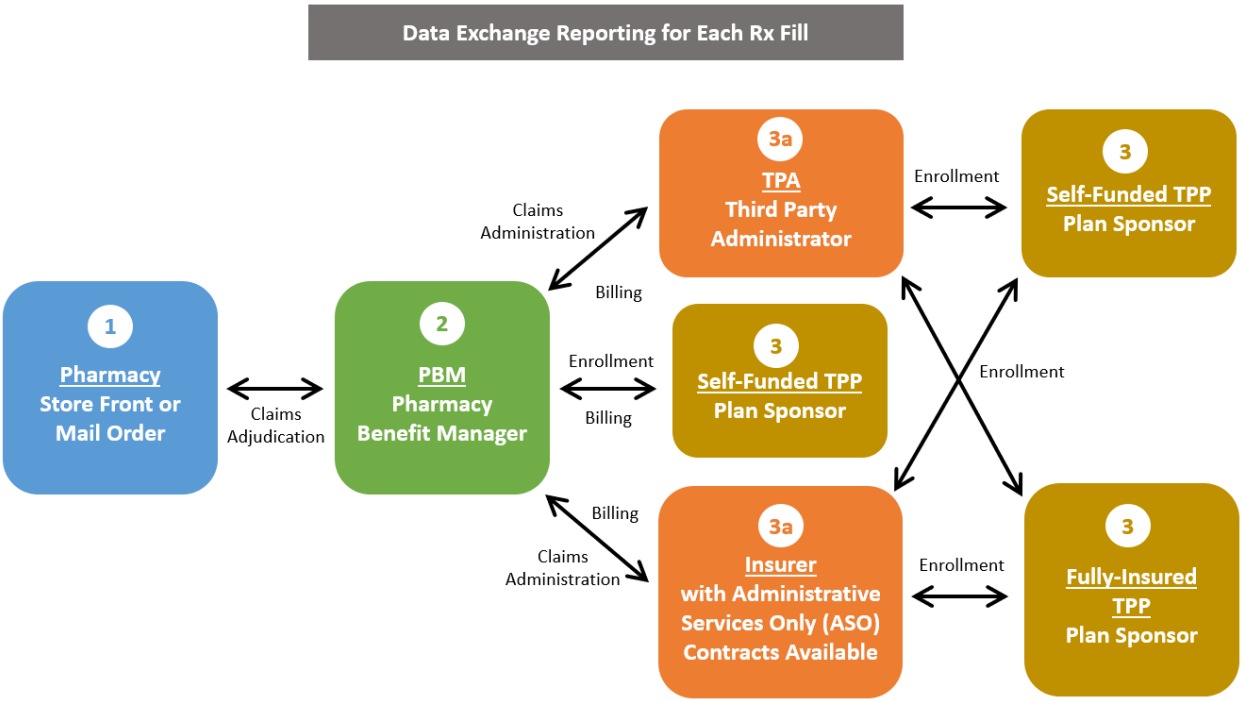
178 Pharmacy Benefit Management Institute, "2017 Trends in Drug Benefit Design," 2017, Figure 11.

179 Pharmacy Benefit Management Institute, "Prescription Drug Benefit Cost and Plan Design Report 2013-2014," 2013, Figure 3.

180 Pharmacy Benefit Management Institute, "Prescription Drug Benefit Cost and Plan Design Report 2013-2014," 2013.

181 Craft Declaration, at ¶ 68.

Figure 3
Claims Adjudication Data Exchange Process with Intermediaries



99. For example, self-insured TPPs may contract with an intermediary to receive administrative services, but not actual insurance coverage, even though the intermediary provides both options. Anthem is an example of an insurer that provides both fully insured solutions and ASO services; MADA is a self-funded TPP that contracted with Anthem only to receive administrative services.[182] AmeriBen is an example of a TPA that provides both fully insured solutions and ASO services.[183] Claims data alone do not provide insight into the contractual relationships or distinguish among TPAs or insurers that are servicing a self-funded health plan and/or a fully insured health plan, and therefore cannot be used to identify TPP class members.

100. As a result, it is necessary to first identify intermediaries in the claims data and then determine what role the intermediary is playing: either an insurer, in which case

182 Anthem, "Small Business Health Plans," available at https://www.anthem.com/employer/health-insurance/small-business-plans/; Cobb Deposition, Anthem Health Plans of Maine, p. 42:5-19.

183 AmeriBen appears in the Xponent data used by Plaintiffs' experts. Craft Backup Production, file "TPP Lists.xlsx"; AmeriBen, "Our Company," available at https://ameriben.com/company#about-ameriben (AmeriBen provides "complex benefit plans for over 100 self-funded employer groups and fully insured university plans totaling over 900,000 member lives.").

the insurer would be the TPP class member, or as an ASO, in which case the underlying plan sponsor that contracted with the ASO would be the TPP class member.

101. Identifying the correct intermediaries in the data is also complicated by the various clients that PBMs serve. For example, as Ms. Craft notes, because smaller PBMs "may lack a claims processing system," larger PBMs may provide services to smaller PBMs.[184] To illustrate, the OptumRx 2021 payer sheet for commercial and Medicaid clients referenced above in **Figure 2** indicates that OptumRx provides claims adjudication services for ProAct, a smaller PBM, under BIN "017366" and PCN "9999." There are no NCPDP fields that would allow for differentiation between these types of payors and intermediaries, or that would allow for identification of a payors' funding status (self-insured vs. fully insured) in the PBM claims data. Identifying whether a payor is self-insured or fully insured requires individualized review of the PBM plan set-up documents and the TPA's contractual relationship with their client. None of this information is available using the data Plaintiffs' expert has proposed.

102. It is also likely that the PBM does not maintain information about the underlying plan sponsor when its client is an independent TPA, because the TPA is the organization responsible for paying the PBM for its pharmacy claims. In my experience, PBMs typically require payment from TPAs within one or two days, and in some instances require an escrow of money that is drawn down and replenished by the TPA. In such cases, the PBM does not receive payment from the TPP or have an agreement with the TPA's clients. Furthermore, TPAs may provide services to other TPAs, further complicating the identification of the underlying payor. For example, [redacted].[185] The PBM may not maintain information about [redacted] self-funded clients, let alone information about [redacted]. Based on my industry experience, TPAs generally want to avoid providing their client information directly to a PBM because the PBM could target the TPAs' clients directly with the PBM's sales force.

184 Craft Declaration, at footnote 31.

185 Craft Backup Production, file "TPP Lists.xlsx"; [redacted]

103. To my knowledge, no PBM data containing TPP-identifying information have been produced in this case that would allow one to test Ms. Craft's assertions related to how self-funded or fully insured payors could be programmatically identified.[186]

104. Ms. Craft simplifies these complex contractual arrangements by stating that "PBMs should be expected to know the capacity in which their clients are contracting (whether on behalf of themselves or as an ASO/TPA for a self-funding TPP)."[187] However, based on my experience in the industry, this information is not readily available, and Ms. Craft presents no evidence that PBMs consistently maintain this information throughout the entire class period.

105. In my experience, PBMs transfer claims data from their claims processing system to an accounting system that performs the client billing and reconciliation functions. The claims processing system contains minimal client information, which facilitates response times for processing claims. The client information is instead stored in set-up sheets, which are inputs into the PBM's accounting system that allow the PBM to charge their clients. Although the billing and payment information in the accounting system could be mapped to the claims data, it is not necessarily the case that the PBM maintains historical billing and payment information that could be matched to the claims data. TPPs may switch TPAs or change their funding options (self-funded/fully insured) status throughout the class period. As a result, in addition to the fact that Ms. Craft would require data from multiple systems maintained by the PBM that follow different proprietary formats that are not consistent across different PBMs, the information identifying the relevant TPP throughout the relevant time period (as opposed to just the current billing information) is not necessarily available.

106. Furthermore, each PBM may retain information about a particular client for a different period of time, depending on their business needs. In fact, Ms. Craft seems to acknowledge that programmatically identifying TPP class members may not be possible

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186 I understand that the [redacted] *See, e.g.,* Conti Backup Production, file "000000_Original1014066.XLSX."

187 Craft Declaration, at ¶ 68.

without individualized research into the ASOs and TPAs that appear in the PBM data, as she claims that identification of the correct TPP could be left to the claims administrator, who would ask the TPP and TPA to resolve the issue.[188] This, however, is not an administratively feasible solution. The Society of Professional Benefit Administration ("SPBA") estimates that it has nearly 440 TPA members, which administer health plans covering approximately 40 percent of U.S. workers, dependents, and retirees.[189] The claims administrator would be required to individually contact potentially hundreds, if not thousands, of TPAs and TPPs to request that they identify their funding status (self-insured vs. fully insured), review, and then reconcile all of their claims for each of the at-issue VCDs across the class period.

107. Ms. Craft suggests that other data sources could be used to supplement the PBM data to identify TPAs: asking PBMs to identify TPAs; asking insurers to identify accounts for which they are acting as an ASO or insurer; using the list of organizations identified as TPAs in the Xponent data; or using publicly available lists of TPAs.[190] However, Ms. Craft fails to recognize that combining information from different data sources would require matching names manually between these sources, and Ms. Craft does not propose a methodology for linking these disparate data sources. In my experience, there is no uniform list of TPAs used industry-wide. The names of these organizations are therefore likely recorded differently between the various data sources described by Ms. Craft. There is no data map to easily link between these sources, thus preventing an automated review of the entities appearing in the claims data and instead necessitating an individualized review of each name to merely to identify each TPA or ASO.

108. Moreover, publicly available lists may not be complete. As noted above, the SBPA has nearly 440 TPA members, but the SBPA further notes that qualifying for

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188 Craft Declaration, at ¶ 68 ("If for some reason a TPA/ASO and TPP were each to submit a claim for the same purchases after a successful judgment or settlement, that duplication would immediately be apparent simply by matching the plan number and date range. The claims administrator could then simply notify claimants and require them to resolve the dispute.").

189 Society of Professional Benefit Administrators, "A Brief History of SPBA," available at https://spbatpa.org/article/brief-history-spba.

190 Craft Declaration, at ¶¶ 68-70.

membership requires an entity to derive at least half of their income from TPA services and that SPBA turns away 200 TPA applicants each year for failing this membership criteria.[191]

c) IQVIA Xponent Data Are Too Aggregated to Identify Relevant TPPs

109. Ms. Craft also references the IQVIA Xponent data as a potential source for identifying class members,[192] and Dr. Conti relies on IQVIA Xponent data for her calculations of manufacturer damages.[193] Although IQVIA data are relied on by the industry for monitoring overall trends and other business reasons, IQVIA data are not designed or suited for the identification of TPP class members. Nevertheless, Ms. Craft performed "[a]n analysis of the Xponent data obtained [by Plaintiffs] in this case [that] shows [redacted]"[194] In this estimate, Ms. Craft fails to identify TPPs that meet the proposed class definitions. Moreover, her estimate is inconsistent with the TPPs that Dr. Conti includes in her damages calculations.

110. The IQVIA Xponent data cannot be used to distinguish between fully insured and self-funded payors. Ms. Craft references the [redacted]

191 Society of Professional Benefit Administrators, "A Brief History of SPBA," available at https://spbatpa.org/article/brief-history-spba.

192 Craft Declaration, at ¶ 72.

193 Conti Declaration, at ¶ 55.

194 Craft Declaration, at ¶ 72.

195 Craft Declaration, at ¶¶ 61, 70.

196 Conti Backup Production, file "IQVIA Plan Model Type Listing.xlsx." As discussed in **Section III.B**, IQVIA [redacted]

[redacted][197] Without information related to the self-funded/fully insured status of these payors, the Xponent data cannot be used to identify proposed TPP class members.

111. Additionally, the [redacted][198]

112. Similarly, the IQVIA Xponent data note [redacted][200] Nevertheless, Ms. Craft improperly includes these entities in her count of TPPs, without attempting to ensure that they represent actual class members. For example, [redacted]"[201] Under Plaintiffs' proposed class definitions, [redacted] is not included in the class, but [redacted] may be; however, the Xponent data are not granular enough to identify those underlying clients to determine whether or not they are in fact proposed class members.

197 Backup production to this report.

198 Conti Backup Production, file "IQVIA Plan Model Type Listing.xlsx."

199 Conti Backup Production, file "IQVIA Plan Model Type Listing.xlsx."

200 Backup production to this report.

201 Craft Backup Production, file "TPP Lists.xlsx."

113. Dr. Conti also includes prescriptions associated with these entities in her damages calculations. PBMs, TPAs, and processors account for [redacted][202]

114. The Xponent data are therefore too aggregated to accurately identify TPPs. As the above examples show, Ms. Craft's estimate of the number of TPPs is inaccurate and it wrongly includes PBMs (contrary to the class definition), demonstrating the difficulty of ascertaining the correct TPP class members.

115. Ms. Craft's estimate of TPPs is also inconsistent with Dr. Conti's damages methodology. For example, Ms. Craft identifies and excludes "other third party plans," which includes payers identified in the IQVIA Xponent data [redacted][203] IQVIA lacks the necessary information to link these claims to a specific payor.[204] These entities, however, are *included* in Dr. Conti's manufacturer damages calculations, and account for about eight percent of the at-issue VCD prescriptions.[205] Without additional data or information about these plans, Ms. Craft and Dr. Conti are unable to identify what health plans these prescriptions are associated with and whether or not they are TPP class members because information on the plan name (let alone information on the plan's self-funded/fully insured status) is not reported by IQVIA.

116. Lastly, there is no information in the IQVIA Xponent data that would allow for identification of members of the proposed Wholesaler Defendant-specific sub-classes. These aggregated data provide no information related to which prescriptions involved distribution by a Wholesaler Defendant.

d) Other Data Sources Referenced by Ms. Craft Are Insufficient for Identifying TPPs

117. Ms. Craft also makes references to other sources that she indicates can be used to identify TPPs, without specifying a methodology for how she would apply these sources to identify proposed TPP class members: the IRS Form 5500 filings and lists

202 Backup production to this report.

203 Backup production to this report.

204 Conti Backup Production, file "IQVIA Plan Model Type Listing.xlsx."

205 Backup production to this report.

compiled by claim administrators in pharmaceutical end-payor cases.[206] The IRS Form 5500 would be wholly insufficient for identifying relevant TPP class members as there is no reliable and administratively feasible way to combine the claims data and the Form 5500 data, let alone include or exclude TPPs based on funding type.

a. First, relying on the IRS Form 5500 data would result in an incomplete list of proposed class members because not all organizations are required to file a Form 5500 for the health plans that they offer. Specifically, the Form 5500 instructions state that "welfare benefit plan[s] that cover fewer than 100 participants as of the beginning of the plan year and [are] unfunded, fully insured, or a combination of insured and unfunded" are exempt from filing a Form 5500, where unfunded refers to plans with "benefits paid as needed directly from the general assets of the employer or employee organization that sponsors the plan."[207] Approximately five million private firms in the U.S. have fewer than 100 employees, indicating that the Form 5500 likely does not include information for many eligible TPP class members.[208]

b. Second, identifying whether employers are fully insured or self-funded requires interpreting organizations' funding sources and making assumptions related to the funding for their pharmacy benefits to identify the relevant TPP class members. Form 5500 merely requires organizations to report the sources of its funding: if an organization offers multiple types of benefits (e.g., health, pension, etc.), it is not clear which of the specified sources of a plan's funding applies to its pharmacy benefit component.[209] The Department of Labor takes the Form 5500 filings and categorizes organizations as self-funded, fully-insured, or mixed-funded using an

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206 Craft Declaration, at footnote 30.

207 U.S. Department of the Treasury, Department of Labor, and Pension Benefit Guaranty Corporation, "Instructions for Form 5500," 2020, available at https://www.dol.gov/sites/dolgov/files/EBSA/employers-and-advisers/plan-administration-and-compliance/reporting-and-filing/form-5500/2020-instructions.pdf.

208 U.S. Bureau of Labor Statistics, "Table G. Distribution of Private Sector Firms by Class Size," available at https://www.bls.gov/web/cewbd/table_g.txt.

209 U.S. Department of Labor, "Self-Insured Health Benefit Plans 2019 Based on Filings through Statistical Year 2016," January 2019, available at https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2019-appendix-b.pdf, p. 12.

algorithm and assumptions; nevertheless, the Department of Labor cautions that "the classification [of funding] in this report should not be interpreted as an official or legal definition."[210]

c. Third, the Form 5500 data would need to be combined with claims data to identify organizations that paid for the at-issue drugs, because the Form 5500 data do not include information on the prescriptions purchased by each entity. As discussed above, combining data sources would not be an automated process due to the differences in how TPPs' names are recorded in each data source [redacted], and would require a manual review of each plan to ensure the information from the Form 5500 data was combined with information from the claims data correctly. Given these limitations to the Form 5500 data, this data source is also insufficient for identifying proposed TPP class members, either alone or in combination with other data sources.

118. With respect to the lists compiled by claim administrators in pharmaceutical end-payor cases, Ms. Craft has provided no evidence or explanation for how these lists were compiled and whether these lists correspond with the proposed class definitions in this matter. Any list provided by claim administrators would need to be combined with claims data in this matter, which, again, is a burdensome process requiring manual review. Furthermore, Ms. Craft has not provided any such list in this case for me to test or validate her claims related to the reliability of these lists for determining proposed TPP class members.

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210 Appendix B was prepared by Advanced Analytical Consulting Group at the request of the Department of Labor ("The U.S. Department of Labor (DOL) engaged Advanced Analytical Consulting Group, Inc. (AACG) to assist with the ACA mandate. This document is intended to serve as an appendix to the Secretary's 2018 *Report to Congress*," p. 1). *See* U.S. Department of Labor, "Annual Report on Self-Insured Group Health Plans," March 2019, available at https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2019.pdf, p. 4; U.S. Department of Labor, "Self-Insured Health Benefit Plans 2019 Based on Filings through Statistical Year 2016," January 2019, available at https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2019-appendix-b.pdf, p. 10.

2. Members of the Proposed Medical Monitoring Classes Cannot Be Identified Without Individual Review of Their Prescription Histories

119. Ms. Craft claims that "[d]ata produced in this case by the eight Pharmacy Defendants and Humana Pharmacy confirms [her] opinion that electronic records systematically identify the consumer Class Members."[211] First, the data produced in this matter exclude customers of, and are unlikely to be representative, of the 21,000+ independent pharmacies in the U.S. in 2018,[212] which I discuss more extensively in **Section IV.C**. Second, Ms. Craft fails to address issues specific to identifying members of the proposed medical monitoring classes. Specifically, under Plaintiffs' definition, consumers are required to have "a sufficiently high Lifetime Cumulative Threshold of NDMA, NDEA, or other nitrosamine, in generic valsartan-containing drugs."[213] Although Ms. Craft claims that it is possible to create "a consumption record for individual consumers,"[214] in fact, the pharmacy data produced in this matter are insufficient to create this record due to the unavailability of lot number information and due to the inability to systematically track patients across disparate pharmacy data systems and over time.

120. As I discuss in **Section IV.C** below, lot number information is not available at the patient level. This lack of lot number information presents a particular hurdle for identifying consumer members of the medical monitoring classes because, as discussed in **Section I.B**, the level of NDMA or NDEA in VCDs, to the extent there was any, varied by lot. Some of the recalls, such as those by Aurobindo, occurred at the lot-level and were specific to lots within a range of expiration dates,[215] rather than the NDC-level, further creating variations in the NDMA and NDEA levels that any individual patient may have consumed. As discussed in **Section IV.C**, consistent with current legal requirements, lot number and expiration date are not available at the patient level consistently throughout the class period. [redacted]

211 Craft Declaration, at ¶ 49.

212 National Community Pharmacists Association, "2019 NCPA Digest, Changing the Pharmacy Payment Model," 2019 ("2019 NCPA Digest"), available at http://www.ncpa.co/pdf/digest/2019/2019-digest.pdf, p. 9.

213 Plaintiffs' Motion for Class Certification, at Exhibit C.

214 Craft Declaration, at ¶ 51.

215 Auro-MDL 2875-0020705-0754 at 0706.

[redacted][216]

121. The limited lot number and expiration date information demonstrates the importance of distinguishing between lots within an NDC. For example, [redacted][217] [redacted][218] Without the ability to identify product lots and expiration dates down to the patient level, it is impossible to accurately determine the level of exposure to impurities experienced by individual patients to assess this "sufficiently high Lifetime Cumulative Threshold."

122. Additionally, the available pharmacy data represent data on *dispensed* prescriptions, rather than data on the actual consumption of medications by individuals. In a 2015 study of insured adults with hypertension, almost one third of U.S. adults were found to be nonadherent to their anti-hypertensive medication regimen.[219] Consequently, even if specific lots could be traced to specific patients, reliance on the prescription claims data may overstate consumers' actual exposure to NDMA and NDEA from at-issue VCDs.

123. Lastly, creating "a consumption record for individual consumers" would require tracking consumers who may have received their prescriptions at different pharmacies and who may have switched pharmacy benefit providers due to changes in employers. Ms. Craft acknowledges that each pharmacy assigns their customers to a different customer identifier,[220] which cannot be mapped across different pharmacy data platforms. In other words, one person would have a different customer identifier at each

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216 *See* **Table 4**; Backup to Craft Declaration, files "Valsartan_Dispensing_Data_2012_2016.xlsx," "Valsartan_Dispensing_Data_2017.xlsx," and "Valsartan_Dispensing_Data_2018.xlsx."

217 Backup production to this report.

218 Backup production to this report.

219 Chang, Tiffany et al., "National Rates of Nonadherence to Antihypertensive Medications Among Insured Adults with Hypertension, 2015," *Hypertension,* Vol. 74, No.6, November 2019, pp. 1324-1332.

220 Craft Declaration, at ¶ 50 ("However, some of these consumers may have made additional purchases at other pharmacies that assigned them a different Customer ID.").

pharmacy chain where they filled an at-issue VCD prescription. This is consistent with my experience in the industry: each software package used by different pharmacies assigns separate unique patient identifiers and there is no administratively feasible method to identify individual patients across data sources. There is no universal patient identifier that has been adopted industry-wide, even though such an identifier has been proposed by the NCPDP. Consequently, Ms. Craft does not attempt to combine the various different datasets across pharmacies to de-duplicate the number of unique consumers in her Table 7. Instead, Ms. Craft claims that "[o]nce personal identifying information linked to Customer IDs is produced, it will be possible to link these consumers and their purchases across multiple pharmacy platforms using name, date of birth and address."[221] Ms. Craft vastly oversimplifies this manual process: consumers may change their address over time and even their names—the likelihood of this occurring frequently over the entire class period is very high.

124. Indeed, a 2018 publication by the Pew Charitable Trusts examining patient electronic medical records suggests that matching a given patient's records even *within the same organization* requires a complicated process involving manual review. The report found that, on average, 18 percent of healthcare organizations' patient records are duplicated within the same organization.[222] This implies that matching patient records *across organizations* that maintain data in different formats and databases would lead to substantially more duplicate patient records that would require manual review. Moreover, while the report suggests that internal patient record-matching rates can reach upwards of 80 or 90 percent within an organization through the use of algorithms that are "…fine-tune[d]…based on the unique aspects of their patient populations," challenges such as the lack of standardization in the way addresses are recorded (e.g., on one line or two), typos, un-entered data, patients with similar information, and patients' information changes can make it very difficult to match patients' records between different organizations.[223] Ms.

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221 Craft Declaration, at ¶ 50.

222 Pew Charitable Trusts, "Enhanced Patient Matching Is Critical to Achieving Full Promise of Digital Health Records," October 2, 2018, available at https://www.pewtrusts.org/en/research-and-analysis/reports/2018/10/02/enhanced-patient-matching-critical-to-achieving-full-promise-of-digital-health-records ("Pew Charitable Trusts Study 2018").

223 Pew Charitable Trusts Study 2018.

Craft has neither proposed the use of an algorithm in her report nor described a methodology for developing one, and even if she had, the Pew Charitable Trusts' publication notes that when algorithms were used, it still "required some amount of manual review to adjudicate complicated linkages."[224]

125. Matching consumers by name, date of birth, and address over multiple different pharmacy data systems is therefore far from an automatic programming exercise, but instead requires substantial manual matching between millions of claims records.

126. Ms. Craft also points to other data sources, such as non-Defendant pharmacies, TPP data, or PBM data.[225] These data sources would be subject to the same issues with respect to identifying consumers across data platforms, as consumers may change employers and health plans over time. TPP and PBM data would also not allow for the identification of uninsured and/or cash-paying consumers. As a result of these data challenges and the data available in the industry today, creating a "consumption record for individual customers" to determine whether each consumer reached the "sufficiently high Lifetime Cumulative Threshold" of NDEA and NDMA as a result of their consumption of the at-issue VCDs simply is not feasible.

B. Data Produced in this Matter Demonstrate that Common Data Are Not Available to Reliably Apply Class Exclusions in an Administratively Feasible Manner

127. Ms. Craft claims that "[t]he data used in processing claims (including data stored with PBMs responsible for claims adjudication and with pharmacies) is sufficient when combined with public records to carry out the Proposed Class exclusions."[226] Ms. Craft, however, fails to provide details on the methodology she would use to combine the data with public records to programmatically apply relevant class exclusions. Instead, the available data indicate that an impractical, laborious, and manual process would be required to reliably supplement the claims data and apply the relevant class exclusions. Accordingly, Ms. Craft has not applied all of the relevant class exclusions in her analyses, and in some

224 Pew Charitable Trusts Study 2018

225 Craft Declaration, at ¶ 52.

226 Craft Declaration, at ¶ 53.

cases, Ms. Craft's interpretation of the relevant class exclusions differs from Dr. Conti's interpretation.

1. State Government Entities Cannot Be Reliably Identified to Be Excluded from the TPP Class in an Administratively Feasible Manner

128. Ms. Craft states in her declaration that "Federal and State government entities are excluded from the Proposed Classes,"[227] and further elaborates that self-funded state entities should be excluded from the TPP class.[228] However, Ms. Craft fails to propose a cohesive methodology for excluding self-funded state entities using the various datasets that she mentions. In fact, Ms. Craft and Dr. Conti apply inconsistent exclusions for state entities while using the same Xponent dataset, demonstrating that the definition of what constitutes a state entity is not consistently understood by Plaintiffs. Plaintiffs' experts' differences in methods further demonstrate that the available data in this matter are insufficient for systematically excluding state entities. Instead, an individualized review of these entities is required to determine which ones should be included or excluded from the proposed TPP class.

129. First, Plaintiffs' experts are inexplicably inconsistent in how they treat Medicaid managed care plans: Dr. Conti *excludes* all Medicaid plans from her damages methodology,[229] while Ms. Craft *includes* Medicaid managed care plans ([redacted]) and *excludes* Medicaid fee-for-service plans ([redacted]) in her count of TPPs.[230]

130. Second, although Ms. Craft uses the [redacted] Xponent data for some exclusions,[231] she ignores the [redacted] in her exclusion of state entities, which is defined by the IQVIA data dictionary as [redacted][232] In contrast,

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227 Craft Declaration, at ¶ 55.

228 Craft Declaration, at ¶ 62.

229 Backup Production to Conti Declaration.

230 Backup production to this report.

231 Ms. Craft excludes payors [redacted] in estimating the number of TPP class members. *See* Craft Declaration, at ¶ 72 and backup production to this report.

232 Conti Backup Production, file "IQVIA Plan Model Type Listing.xlsx."

Dr. Conti specifies a list of 111 individual state plan names to exclude from her damages calculations, all of which *do* [redacted][233] Dr. Conti provides no explanation for why she chose to exclude some state employees but not others, demonstrating that individualized research was required into each of these state exclusions for her to make these determinations and that individualized research is required to verify Plaintiffs' methodology. For example, [redacted][234] Dr. Conti *excludes* [redacted] but *includes* [redacted] without an explanation.[235]

131. As a result of the differences in Plaintiffs' experts' methodologies for applying this class exclusion, they are inconsistent in their inclusion or exclusion of individual entities. For example, research into [redacted] suggests that it represents the [redacted], which was self-funded as of 2020.[236] To the extent that this organization is considered to be a state entity, it should be excluded from the TPP class as a self-funded state entity under Ms. Craft's reasoning,[237] but Ms. Craft *includes* this entity in her TPP count, while Dr. Conti *excludes* it from her damages calculation.[238] This is just one example of the complexity associated with identifying state entities and the discrepancy between the methodologies proposed by Ms. Craft and Dr. Conti.

132. Reliance on the [redacted] IQVIA Xponent data is not sufficient to identify all relevant state entities to exclude from the proposed TPP classes. A payor can be associated with multiple [redacted]

233 Conti Backup Production, file "State_Emps_List.xlsx."

234 Conti Backup Production, file "State_Emps_List.xlsx."

235 Conti Backup Production, file "State_Emps_List.xlsx."

236 New York State Nurses Association, "Benefits Fund Annual Report," 2020, available at https://www rnbenefits.org/Portals/1/Assets/Benefits/Documents/Benefits%20Fund%202020%20AR.pdf.

237 Craft Declaration, at ¶ 62.

238 Craft Backup Production, file "TPP Lists.xlsx"; Conti Backup Production, file "State_Emps_List.xlsx."

[239] Dr. Conti excludes all prescriptions associated with but keeps prescriptions associated with [240] Dr. Conti provides no explanation as to why some prescriptions but not others associated with the same payer should be included in her damages calculation. Ms. Craft similarly counts as a payer in her estimates of the number of TPPs.[241] However, Ms. Craft cites to a list published by the National Conference of State Legislatures ("NCSL") that lists as offering all self-funded health plans, which Ms. Craft states should be excluded from the IQVIA Xponent data.[242] Ms. Craft fails to follow her own methodology in applying the relevant state exclusions when estimating the number of TPPs.

133. As another example of the unreliability of the for identifying state exclusions for the purposes of the proposed TPP class, also appears in the IQVIA Xponent data, associated with [243] Although IQVIA does not classify this payor as a state entity (and both Ms. Craft and Dr. Conti include this payor as a TPP in their proposed methodologies), considers employees of the to be state employees,[244] and therefore, should be excluded from the proposed TPP class. Both Ms. Craft and Dr. Conti fail to follow the methodology Ms. Craft put forward (i.e., consulting the NCSL and identifying the relevant self-funded state entities to exclude), and these examples demonstrate the individualized research required to implement Ms. Craft's proposed methodology related to leveraging multiple different data sources for state exclusions.

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239 *See* Conti Backup Production, file "IQVIA Plan Model Type Listing.xlsx."

240 The Conti Backup Production, files "IQVIA Plan Model Type Listing.xlsx" and "IQVIA Managed Care Workbook - November 2020.xlsx." *See also* backup production to this report.

241 Craft Backup Production, file "TPP Lists.xlsx."

242 Craft Declaration, at ¶ 62 and Figure 8.

243 Conti Backup Production, file "IQVIA Managed Care Workbook - November 2020.xlsx."

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Case 1:19-md-02875-RMB-SAK Document 2040-6 Filed 05/05/22 Page 77 of 127 PageID: 68713

Restricted Confidential

134. Ms. Craft cites other sources and methods as well, but does so without demonstrating a methodology to combine relevant information across these different data sources because it would require a similar individualized process.[245] Ms. Craft states that the process of excluding state employee health plans could be "refined" by comparing plan names in the Xponent data "to the Milliman plan-by-plan list for each State."[246] Ms. Craft cites to the Milliman Atlas data, but does not propose a methodology for how to systematically use this source to identify the state entities that need to be excluded from the proposed TPP class. In fact, Ms. Craft does not present or analyze the Milliman data to see whether her proposed method would even be feasible.[247] If she did, Ms. Craft would likely need to undertake a similarly individualized process as described above with the IQVIA data to reconcile entities appearing in the different data sources with different naming conventions to make the relevant and correct exclusions.

135. Similarly, Ms. Craft asserts that "if any uncertainty remained, a look-up online or a contact to the State's benefits office could confirm funding information."[248] Not only would contacting the benefits office from all 50 U.S. states, the District of Columbia, and Puerto Rico be burdensome, even assuming the information is available, but Ms. Craft would again be required to manually reconcile the information given to her by the individual states about the funding status for all plans offered over the class period with the information in the IQVIA Xponent data (or any other data on prescription claims) to identify the relevant state entities.

136. Lastly, as discussed in **Section III.D**, Medicare Part D plans are at least in large part funded by the federal government, and in my experience, the industry views Medicare Part D plans as a federally-funded plan, as evidenced in the same sources cited by Ms. Craft.[249] To the degree Medicare Part D plans should be excluded under Plaintiffs' class

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245 Craft Declaration, at ¶¶ 60, 62.

246 Craft Declaration, at ¶ 62.

247 Craft Declaration, at ¶ 60.

248 Craft Declaration, at ¶ 62.

249 *See, e.g.,* CVS Health Payor Solutions, "Health Plan Client Engagement Overview," available at https://payorsolutions.cvshealth.com/programs-and-services/health-plan-client-engagement ("For those health plans that offer government programs, such as Medicare and Medicaid, this requires a great deal of expertise on the intricacies of regulatory and compliance operations."); MedImpact, "Who We Serve," available at

definition because they are federally funded, such exclusions are not addressed by Ms. Craft or Dr. Conti. If Plaintiffs seek to include Medicare Part D plans, then the portion of VCD claims reimbursed by the federal government would need to be excluded. Neither Ms. Craft nor Dr. Conti have proposed a methodology to do this programmatically or with the available data.

2. Identifying Defendants' Personnel to Be Excluded from the Consumer Classes Requires Manual Review

137. Ms. Craft claims that the exclusion of "Defendants and affiliated entities, and their employees, officers, directors, and agents" is a "standard exclusion[] common to almost all end payor class actions" and that "Defendants could provide a list" of these individuals.[250] However, Ms. Craft fails to recognize that this case is not a standard end payor class action and involves many Defendants that would make reconciling any list provided by Defendants with data used to identify the class substantially more complex.

138. As discussed in **Section IV.A**, identifying individual consumers over time and across data platforms would require extensive manual review when matching consumers by "name, date of birth, and address" (as Ms. Craft claims she will do);[251] similarly, identifying Defendants' employees that need to be excluded would require identifying millions of potential consumers across disparate claims data sources by name, date of birth, and address over the class period. This would require extensive manual review, even if algorithms were used. As discussed in **Section IV.A**, a 2018 study found that, on average, 18 percent of healthcare organizations' patient records are duplicated within the same organization;[252] any attempt at combining information across disparate data systems from different organizations would likely result in a much higher rate of duplication and a much greater need for manual review. **Table 3** below summarizes the number of current employees who work for only a select number of Retail Pharmacy and Wholesaler

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https://www medimpact.com/clients/who-we-serve (Medicare Part D plan sponsors are mentioned under "Government Programs."); both cited in Craft Declaration, footnote 103. *See also* Craft Declaration, at ¶ 59 ("Kroger Rx Savings Club cannot be in conjunction with any Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs, including any state pharmaceutical programs.") and footnote 108.

250 Plaintiffs' Motion for Class Certification, Exhibit A; Craft Declaration, at ¶ 54.

251 Craft Declaration, at ¶ 50.

252 Pew Charitable Trusts Study 2018.

Defendants, demonstrating the high number of individuals that would need to be identified in claims records.

Table 3
Selected Defendants and Their Currently Reported Number of Employees

Defendant	Number of U.S. Employees
Albertsons[253]	300,000
AmerisourceBergen[254]	16,800
Cardinal Health[255]	29,000
CVS[256]	300,000
Express Scripts[257]	27,000
Kroger[258]	465,000
McKesson[259]	80,000
Rite-Aid[260]	51,000
Walgreens[261]	225,000
Walmart[262]	1.6 million

139. Additionally, consumers may change their employment, such that they are employees of Defendants for part of the class period and employees of other organizations for a different part of the class period (for example, an employee at an independent

253 Albertsons Company, Inc., Form 10-K, February 7, 2021, available at https://sec report/Document/0001646972-21-000026/aci-20210227 htm, p. 10.

254 AmerisourceBergen Corporation, Form 10-K, September 30, 2021, available at https://d18rn0p25nwr6d.cloudfront.net/CIK-0001140859/b47c1896-508a-4d81-9922-ccbd19d08da6.pdf, p.6.

255 Cardinal Health, Inc., Form 10-K, June 30, 2021, available at https://d18rn0p25nwr6d.cloudfront.net/CIK-0000721371/7b1e4511-f728-4423-b557-a23766ff6ab1.pdf, p. 34.

256 CVS Health, "Our Company at a Glance," available at https://cvshealth.com/about-cvs-health/our-company-at-a-glance.

257 Express Scripts, "Innovating for Better: 30+ Years and Counting," available at https://www.express-scripts.com/corporate/about/timeline.

258 The Kroger Co., Form 10-K, January 30 2021, available at https://d18rn0p25nwr6d.cloudfront net/CIK-0000056873/30ee8aa9-7149-428d-b3a2-fb0c15ab36d8.pdf, p. 4.

259 McKesson, "Key Facts," available at https://www.mckesson.com/About-McKesson/Key-Facts/.

260 Rite-Aid, "Our Story," available at https://www riteaid.com/about-us/our-story.

261 Walgreens, "Facts & FAQs," available at https://news.walgreens.com/fact-sheets/frequently-asked-questions.htm.

262 Walmart, "About," available at https://corporate.walmart.com/newsroom/company-facts.

pharmacy switches jobs and becomes an employee at Walgreens). If these consumers' VCD purchases are included in the class when they are not employed by Defendants and excluded when they are, it would be necessary to match each individual's employment history with the timing of their VCD prescriptions to determine which purchases are part of the proposed classes and which purchases are not. Ms. Craft has not addressed this layer of complexity in her proposed methodology.

C. Members of the Wholesaler Defendant-Specific Sub-Classes Cannot Be Reliably Identified Due to the Lack of Lot Tracking Throughout the Pharmaceutical Supply Chain

140. Plaintiffs seek to certify multiple sub-classes of both consumers and TPPs against Wholesaler Defendants. Determining whether any Wholesaler Defendant was involved in the sale of any given at-issue VCD requires tracking a product from the manufacturer through the pharmaceutical supply chain until it ultimately reaches the consumer. However, as I described in **Section III.A**, the flow of products and pharmacy benefit payments is complex and can involve many different subsets of entities in any given transaction. Specifically, pharmacies may acquire some lots of a specific manufacturer's VCDs directly from the manufacturer and other lots from wholesalers. To determine if an at-issue VCD acquired from a Wholesaler Defendant was then sold to a consumer class member or reimbursed by a TPP class member, lot numbers and expiration dates at the patient level are required.

141. Ms. Craft claims that members of these Wholesaler Defendant-specific sub-classes are readily identifiable because the Drug Supply Chain Security Act ("DSCSA") "requires prescription drug manufacturers, wholesalers, repackagers, and pharmacies to '[e]xchange information about a drug and who handled it each time it is sold in the U.S. market.'"[263] Even though Ms. Craft acknowledges that the DSCSA "is still not fully operative," she claims that "significant participants in the pharmaceutical supply chain (such as the wholesalers and retail pharmacies who are Defendants in this case) maintained similar information as a part of their ordinary course of business prior to the enactment of the DSCSA."[264]

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263 Craft Declaration, at ¶ 33.

264 Craft Declaration, at ¶ 34.

142. Although Ms. Craft is correct that NDCs have been readily available throughout the pharmaceutical supply chain, she is mistaken with respect to lot numbers and expiration dates. Lot number and expiration dates were not available for all levels of the pharmaceutical supply chain during the class period to trace a product from the manufacturer through the supply chain to consumers and TPPs, making it impossible to determine members of the proposed Wholesaler Defendant-specific sub-classes.

143. The DSCSA was signed into law in November 2013 and "outlines critical steps to build an electronic, interoperable system by November 27, 2023, which will identify and trace certain prescription drugs as they are distributed within the United States."[265] The Partnership for DSCSA Governance defines interoperability as "the ability of systems and processes to exchange and use information accurately, efficiently, and consistently among trading partners."[266]

144. However, the DSCSA is still in the process of being implemented, and lot number and expiration date tracking to the patient level is not required until November 2023.[267] As a result, lot numbers and expiration dates are only available for parts of the supply chain during parts of the class period. Specifically, it was only starting in January 2015 (with an additional grace period granted to May 2015) that manufacturers were required to send transaction history, transaction information (including a product's lot number), and transaction statements,[268] collectively referred to as "T3" data, to their customers.[269]

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265 FDA, "DSCSA Implementation: Product Tracing Requirements – Compliance Policy," December 2014, available at https://www.fda.gov/media/90397/download ("FDA Guidance for Industry, 2014"), p. 2.

266 The DSCSA 2023 requirements in Section 582(g)(1) of the FDCA include the "interoperable exchange, interoperable verification, and interoperable tracing" throughout the supply chain to patient level. Partnership for DSCSA Governance, "Foundational Blueprint for 2023 Interoperability," Chapter 1 Understanding of Compliance Requirements and Baseline Business Requirements, July 14, 2021, Glossary pp. 2-3.

267 Partnership for DSCSA Governance, "Foundational Blueprint for 2023 Interoperability," Chapter 1 Understanding of Compliance Requirements and Baseline Business Requirements, July 14, 2021, p. 11.

268 FDA Guidance for Industry, 2014, pp. 2-3. *See also* Drug Supply Chain Security Act, Public Law No. 113-54, November 27, 2013, available at https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf, §581(25)-(27).

269 Deposition of Julie Webb, Vice President of Distribution Quality for Medical and Pharmaceutical Distribution at Cardinal Health, October 5, 2021 ("Webb Deposition"), p. 17:7-15.

145. [redacted] [270] However, the DSCSA specifically exempted wholesalers from providing the lot number, initial transaction date, and initial shipment date as part of the T3 data to customers in situations where wholesalers purchased directly from manufacturers.[271] Moreover, Wholesaler Defendants have testified that the T3 data transmitted to pharmacies did not include lot number information during the class period, consistent with the DSCSA's exemption.[272] Pharmacies therefore do not have access to lot numbers or expiration dates in T3 data on purchases from wholesalers. Pharmacies can receive lot numbers and expiration dates on direct purchases from manufacturers, and [redacted] [273]

146. Importantly, any ability to track medications electronically at the lot-level is lost at the patient level. Pharmacies may purchase medications like valsartan in large quantities. Based on my experience, retail pharmacies may dispense a prescription containing medication from different lot numbers to patients. This occurs when a prescription quantity requires the opening of an additional stock bottle of a product to have sufficient quantity to dispense the prescription.[274] As a result, a patient's VCD bottle may

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270 Stipulation, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, MDL No. 2875, United States District Court, District of New Jersey, February 11, 2021 ("Wholesaler Defendants' T3 Data Stipulation"), at ¶¶ 1-5.

271 Drug Supply Chain Security Act, Public Law No. 113-54, November 27, 2013, available at https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf, §582(c)(1)(A)(ii)(I)-(II) ("For purposes of transactions described in subclause (I), transaction history and transaction information shall not be required to include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer.").

272 [redacted] Declaration of Matthew Sample, Vice President of Manufacturing Operations for AmerisourceBergen, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, Civil No. 1:19-md-02875-RBK-JS, United States District Court, District of New Jersey, June 16, 2020 ("Sample Declaration, AmerisourceBergen"), at ¶¶ 4, 13-14; Declaration of Douglas Redinger, Manager, Regulatory Management at Cardinal Health, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, Civil No. 1:19-md-02875-RBK-JS, United States District Court, District of New Jersey, June 16, 2020, at ¶¶ 3, 12-15.

273 Brais Deposition, Humana, September 28, 2021, p. 43:16-21. Deposition of Britt Turner, Kroger, September 30, 2021 ("Turner Deposition"), pp.121:7-122:1.

274 Taylor Deposition, pp. 183:13-184:11. Deposition of Dick Derks, Nicholas Andrew Tallman, Dadrion Gaston and Stacy Zulueta, Walmart, September 27, 2021 ("Derks et al. Deposition"), pp. 238:21-239:3.

include tablets sourced directly from the manufacturer and tablets sourced through a wholesaler, or a bottle may include recalled tablets, tablets not subject to a recall, or a combination of both.[275] With respect to the latter situation, the lack of lot number information at the wholesaler-pharmacy level restricts traceability not only to the wholesaler-level Defendants, but also to any manufacturer-level Defendant(s) that did not recall every lot of VCDs.

147. Because lot number tracking to the patient level is not yet required by the DSCSA, Retail Pharmacy Defendants do not typically maintain lot numbers and expiration dates in their *dispensing* data, which are the data that Ms. Craft proposes to use in her declaration. Specifically, [redacted][276]

148. Ms. Craft states that [redacted];[277] however, [redacted], as shown in **Table 4** below. Furthermore, Steven Taylor from OptumRx testified [redacted][278]

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275 For example, the OptumRx pharmacy claims data [redacted]. *See* backup to Craft Declaration, files "Valsartan_Dispensing_Data_2012_2016.xlsx," "Valsartan_Dispensing_Data_2017.xlsx," and "Valsartan_Dispensing_Data_2018.xlsx." *See also* backup production to this report.

276 Defendant CVS Pharmacy Inc.'s Response to Plaintiffs' Second Amended Sets of Requests for Production of Documents to Retail Pharmacy Defendants, *In Re: Valsartan Products Liability Litigation*, MDL No. 2875, United States District Court, District of New Jersey, August 14, 2020, pp. 3-5; Stimmel Deposition, Walgreens, p.176:5-7; Turner Deposition, Kroger, September 30, 2021, pp. 123:12-124:2; Derks et al. Deposition, Walmart, September 27, 2021, pp. 238:21-239:3; Deposition of Owen McMahon, Vice President of Pharmaceutical Purchasing at Rite-Aid, September 23, 2021 ("McMahon Deposition"), p. 104:1-7.

277 Craft Declaration, at ¶ 46.

278 Taylor Deposition, OptumRx, pp. 197:23-198:11.

Table 4
Claims with Lot Number and Expiration Date Information
[redacted][279]

Year	Claims with Lot No. / Exp. Date	Total Claims	Percent with Lot No. / Exp. Date
[redacted]			

149. Ms. Craft claims further that data from third-party logistics providers "to route and return recalled products could also be used to identify and trace valsartan-containing drugs."[280] Ms. Craft fails to identify any particular logistics provider from whom data might be sourced, and she does not state any method, let alone a viable method, for feasibly and reliably assimilating their data with the other data she proposes to use to ascertain the class. Moreover, testimony from OptumRx demonstrates that [redacted][281] Alternative data sources suggested by Ms. Craft therefore also lack the specificity to trace a product received by a consumer to the wholesaler.

150. Ms. Craft attempts to gloss over the data issues by claiming that "Retail Pharmacies have exclusive or primary relationships with a particular wholesaler, through which most of their purchases are made."[282] However, [redacted]

279 Backup to Craft Declaration, files "Valsartan_Dispensing_Data_2012_2016.xlsx," "Valsartan_Dispensing_Data_2017.xlsx," and "Valsartan_Dispensing_Data_2018.xlsx."

280 Craft Declaration, at ¶ 48.

281 Taylor Deposition, OptumRx, p. 205:2-22.

282 Craft Declaration, at ¶ 46.

[redacted][283] and [redacted] [redacted][284] Similarly, [redacted] [redacted][285] [redacted] Ms. Craft fails to consider or investigate these potential changes in purchasing patterns.

151. As a result, knowing Retail Pharmacy Defendants' general purchasing processes is an insufficient substitute for lot numbers and expiration date tracking to determine members of the proposed Wholesaler Defendant sub-classes, and Ms. Craft has failed to propose a methodology to identify these members without lot number information at the patient level.

D. Ms. Craft Fails to Acknowledge that Obtaining the Necessary Data Is Not Administratively Feasible

152. Ms. Craft does not address the difficulties associated with obtaining the necessary data to identify proposed class members. She simply suggests that the PBM and pharmacy industries are sufficiently consolidated such that "[c]ombining Retail Pharmacy data with data from the largest PBMs could be expected to cover up to 98% of Class purchases,"[286] without any acknowledgement of the time and expense required to obtain the data from these entities and then combine and deduplicate information across disparate data sources. In fact, obtaining the data and combining information across data systems is a substantially complex process that would be expensive, time-consuming, and challenging.

153. Although Ms. Craft states that "the top six PBMs processed between 89% and 96% of U.S. prescription volume annually between 2015 and 2018,"[287] there are over

283 [redacted]
284 [redacted]
285 [redacted]
286 Craft Declaration, at ¶ 32.
287 Craft Declaration, at ¶ 29.

60 PBMs in the U.S.,[288] many of which operate their own claims processing platforms. PBM consolidation over time may make data production and review more difficult as information needs to be pulled and combined from multiple claims processing systems, which have different field naming conventions and meaning. Data reformatting and mapping typically requires knowledge of old systems that may not be available at the PBM as a result of changes in organizational structures. Ms. Craft has not demonstrated that data from different systems can be systematically combined without a manual review to ensure that the interpretation of the data values is consistent across disparate sources.

154. In my experience, when PBMs merge claims processing systems, there are management decisions related to how much data to convert and what data to load into the new claims processing system. In other cases, merged organizations may choose to operate multiple claims systems rather than undergoing a data migration. For example, Express Scripts acquired Medco in 2012,[289] [redacted] As another example, [redacted].[290] In any case, combining data from multiple systems inevitably creates more potential for duplicated records; as discussed in **Section IV.A**, a 2018 study noted that manual review was necessary even with the use of algorithms to match patient records within the same organization, even without the complications of merged systems.[291]

155. Pharmacy data are even less consolidated. According to Ms. Craft, "[t]he top nine [Defendant] Retail Pharmacies collectively accounted for approximately 72% of the nation's prescription drug dispensing revenue [in 2018]"[292] Obtaining the other 28

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288 NAIC, "Pharmacy Benefit Managers," March 16, 2021, available at https://content naic.org/cipr_topics/topic_pharmacy_benefit_managers htm.

289 U.S. Pharmacist, "Express Scripts and Medco Announce Merger," August 19, 2011, available at https://www.uspharmacist.com/article/express-scripts-and-medco-announce-merger.

290 Declaration of [redacted]

291 Pew Charitable Trusts Study 2018.

292 Craft Declaration, at ¶ 31.

percent of data from non-Defendant pharmacy entities will prove difficult, especially as it will also include over 21,000 independent pharmacies in the U.S.,[293] many of which likely use different dispensing management software providers and have organization-specific and system-specific data practices. These independent pharmacies handled a significant number of prescriptions for the proposed individual and TPP proposed class members. Each single independent pharmacy location filled almost 60,000 prescriptions on average in 2018, almost half of which were new prescriptions.[294]

156. Importantly, there is evidence that smaller, independent pharmacies serve different populations than larger, chain pharmacies, such that data obtained only from these chain pharmacies may not be representative of the individuals and TPPs that fill prescriptions at independent pharmacies. In 2018, 74 percent of independent pharmacies served areas with a population less than 50,000.[295] [redacted] In 2018, the share of prescriptions covered by Medicaid was higher at independent pharmacies (17 percent compared to 4 percent), as was the share of cash payers (9 percent compared to 2 percent), while the share of prescriptions covered by commercial, third-party payors was lower at independent pharmacies (37 percent compared to 57 percent).[296]

157. As discussed in **Section III.C**, the cost of a generic medication depends on the network pharmacy agreement, and it is likely that independent pharmacies have different contractual relationships than chain pharmacies. Therefore, the cost for VCDs paid by TPPs at smaller, independent pharmacies is likely different from the cost for VCDs paid by TPPs at larger, chain pharmacies. Obtaining data from independent pharmacies is therefore important, but Ms. Craft does not address how she would combine data from thousands of pharmacies to identify proposed class members.

293 2019 NCPA Digest, p. 9.
294 2019 NCPA Digest, p. 5, Table 1.
295 2019 NCPA Digest, p. 12.
296 2019 NCPA Digest, p. 19, Table 16.

158. Moreover, Ms. Craft's estimate that PBM and pharmacy data can be combined to capture 98 percent of the prescriptions[297] is flawed. Despite acknowledging that PBMs and pharmacies maintain "parallel record[s]," Ms. Craft does not propose any methodology related to how she would combine data sources across dozens of different entities and then ensure that records were not duplicated between PBM and pharmacy data sources. In fact, this process is unprecedented in the industry; health care organizations report difficulties with matching patients' electronic medical records within the same organization, let alone across organizations.[298] The process of deduplicating patient data is highly complex, given that thousands of VCD prescriptions are dispensed in any given day and patients are assigned different identifiers in the individual datasets. Ms. Craft would be required to manually match up patients by "name, date of birth, and address" across disparate data sources,[299] which, in my experience, are likely to maintain the information differently due to abbreviations, misspellings, or name and/or address changes.

159. Additionally, although Medicare Part D plans are required to keep records for ten years,[300] I am not aware of any legal requirements for PBMs to store commercial claims data for a specific time period. Currently, most retail pharmacy regulations require records to be kept for only two to three years, and these requirements vary by state.[301] Under the DSCSA, all trading partners in the pharmaceutical supply chain would be required to maintain data for six years following a transaction; as I mentioned in **Section IV.C**, these requirements have only been implemented gradually since 2015. Furthermore, the NCPDP

297 Craft Declaration, at ¶ 32.

298 Pew Charitable Trusts Study 2018.

299 Craft Declaration, at ¶ 50.

300 "§423.505 Contract provisions," Electronic Code of Federal Regulations, last amended on January 5, 2022, available at https://www.ecfr.gov/cgi-bin/text-idx?SID=a2c43da057c978791f5877956222e72b&mc=true&node=se42.3.423_1505&rgn=div8.

301 For instance, Massachusetts requires all pharmacy records be kept for three years, Nevada requires pharmacy records to be kept for two years, and Kentucky requires pharmacy records be kept for five years. *See* Commonwealth of Massachusetts, "Massachusetts Statewide Records Retention Schedule: Quick Guide Schedule Number 06-18," K7-01, July 2021, available at https://www.sec.state ma.us/arc/arcpdf/MA_Statewide_Records_Schedule.pdf, p.150; Nevada State Board of Pharmacy, "Practice Frequently Asked Questions," available at https://bop.nv.gov/resources/FAQ/Practice_FAQ/; Kentucky Board of Pharmacy, "General Questions," available at https://pharmacy ky.gov/Pages/General-Questions.aspx.

guidelines do not define how and for how long information is maintained by PBMs and pharmacies.

160. Ms. Craft speculates on reasons why PBMs would maintain historical data but has provided no evidence of this occurring. In fact, the OptumRx declaration cited by Ms. Craft from a different litigation suggests that PBMs do not find historical data useful and may in fact archive it due to lack of use: "OptumRx maintains these [claims] records in the regular course of business from January 1, 2012, onward, although claims older than three years are archived and not as readily accessible as more recent claims."[302]

161. Lastly, obtaining claims data from individual TPPs would not be administratively feasible and would require a substantial amount of time and expense. First, identifying all relevant TPPs from which to solicit claims records would first require identifying all relevant TPPs in the class, which, as explained in **Sections IV.A** and **IV.C**, Plaintiffs cannot do. Second, even if Plaintiffs were able to identify the relevant TPPs, obtaining data from each one may require a chain of approval that is time-consuming. Ms. Craft detailed such a process [redacted][303] Even under Ms. Craft's flawed TPP estimate, data would need to be solicited from "more than 3,000 unique TPPs,"[304] some of which may have changed PBMs over the class period. Similarly, combining information across these disparate data sources would prove to be difficult because of the different fields and naming conventions. In fact, Ms. Craft does not attempt to do so even with the Named Plaintiff TPP data, [redacted][305] Obtaining claims data from TPPs is

302 Declaration of Non-Party OptumRx, Inc., *In Re: Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litigation*, MDL No. 2819, April 4, 2019, at ¶ 8.

303 Craft Declaration, at ¶ 37.

304 Craft Declaration, at ¶ 72.

305 *See, e.g.,* MSP_0001548; ANTM_MADA_SUBP_00000416.

therefore not practical or administratively feasible, and Ms. Craft, again, has not proposed a methodology for combining and interpreting information across different data sources.

V. Dr. Conti's Over-Simplified View of the Prescription Drug Industry and Use of Generic VCDs Leads to Inaccurate Conclusions Which Demonstrate the Need for Individual Inquiry

162. Dr. Conti was retained by Plaintiffs' counsel to "provide opinions and calculations regarding the injury and damages incurred by Classes of consumers and end-payors."[306] According to Dr. Conti, members of the proposed classes suffered economic losses because "the at-issue Valsartan products sold by the Defendants and purchased by consumers and end-payors lacked the assurance that they had the safety, identity, strength, quality, or purity that they were represented to possess to consumers and other payers, contrary to the Federal Food, Drug, and Cosmetic Act ('FDCA'), 21 U.S.C. § 351."[307] She concludes that all VCDs "have no economic value, they are worthless." As such, Dr. Conti describes a method for calculating "damages" based on the total dollar amounts paid by members of the proposed classes for prescriptions of generic VCDs from January 1, 2012, until the recalls in 2018 and 2019.

163. However, as I explain in this section, Dr. Conti's assumption that at-issue VCDs are "worthless" is inconsistent with the sources of value that are considered by P&T committees specifically and the pharmaceutical industry generally. Moreover, her calculations do not reflect the prices paid by proposed class members, or the revenues and costs to Retail Pharmacy Defendants and Wholesaler Defendants. Ultimately, her proposed methodology fails to account for the complexities in the pharmaceutical industry and does not reflect the alleged damages to proposed class members.

A. Dr. Conti's Damages Calculation Baselessly Assumes that Proposed Class Members Received No Benefit from Purchasing Generic VCDs

164. VCDs are maintenance drugs that are prescribed and taken by patients to mitigate the risks of hospitalization and other costly procedures associated with hypertension. From an industry perspective, the efficacy of those drugs defrays substantial

306 Conti Declaration, at ¶ 1.

307 Conti Declaration, at ¶ 4.

costs and/or adverse health outcomes, which is a primary source of benefits to proposed class members associated with taking these drugs. Consistent with this perspective, actions of multiple industry participants, from regulatory agencies to health insurers to individual consumers, demonstrated that VCDs still offered clinical value. Dr. Conti, however, fails to acknowledge and incorporate any evidence of this value into her proposed damages methodology.

165. I have seen no evidence that the efficacy of generic VCDs for consumers was affected by the alleged impurities.[308] First, the efficacy of generic VCDs is demonstrated by consumers' consistent use of these medications in the years prior to the recalls. Testimony of economic loss class representatives, including discussions of their medical records containing blood pressure readings before and during the use of VCDs, established that VCDs were generally effective in controlling their blood pressure.[309] In some cases, the VCDs were even the most effective medications among those that patients had tried. For example, [redacted][310] Second, several of the economic loss class representatives continued to take recalled VCDs until they were able to obtain an alternative medication. These class representatives understood the risks of stopping the medication without a replacement, stating that [redacted] and continued the medication for their

308 Deposition of Michael Bottorff, Professor and Department Head of Pharmacy Practice at Manchester University (Defendants' Scientific Expert), September 16, 2021, pp. 14:3-15:5.

309 *See, e.g.* [redacted]

310 Deposition of [redacted]

[redacted][311] In contrast, other class representatives stopped taking recalled VCDs immediately.[312] As such, even from the class representatives, as examples, it is evident that some individuals attributed value to taking the at-issue VCDs, even after they became aware of the existence of impurities in certain lots, while others did not. Dr. Conti fails to account for this variation in consumers' attitudes.

166. The health benefits of the at-issue VCDs (and the high risk of discontinuing use) was reinforced by the FDA's clear guidance to consumers of recalled VCDs to continue using their medicine until they could obtain a replacement product, as I mentioned in **Section I.B**.[313] Mirroring the FDA's guidance for patients, manufacturer recalls, such as those by Teva, Torrent, and Solco, informed consumers to contact their healthcare provider about alternative treatment, but to continue taking their medication in the meantime.[314]

167. Similarly, P&T committees at PBMs and health insurers did not appear to conclude that the at-issue VCDs lost all value. [redacted].[315] These actions illustrate that health plans and health plan sponsors, such as the TPP proposed class

311 [redacted]

312 *See, e.g.,* [redacted]

313 FDA, "FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity," July 13, 2018, available at https://www fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity.

314 MSP-SUMMACARE-005888-5912, at 5893, 5903-5904; FDA, "Prinston Pharmaceutical Inc Issues Voluntary Nationwide Recall of Valsartan and Valsartan HCTZ Tablets Due to Detection of a Trace Amount of Unexpected Impurity, N-Nitrosodimethylamine (NDMA) in The Products," July 16, 2018, available at https://www fda.gov/safety/recalls-market-withdrawals-safety-alerts/prinston-pharmaceutical-inc-issues-voluntary-nationwide-recall-valsartan-and-valsartan-hctz-tablets.

315 MSP-SUMMACARE-000469-0561; MSP-SUMMACARE-000562-0675; MSP-SUMMACARE-000676-0857; MSP-SUMMACARE-000858-1027; MSP-SUMMACARE-001028-1196; ANTM_MADA_SUBP_00000883-0892; ANTM_MADA_SUBP_00000526-0535; ANTM_MADA_SUBP_00001070-1132; ANTM_MADA_SUBP_00000595-0657; ANTM_MADA_SUBP_00000658-0722; ANTM_MADA_SUBP_00000723-0786; MADA000352-0355 at 0354.

members, understood that the at-issue VCDs continued to offer therapeutic value and that the benefits associated with continuing to take recalled VCDs outweighed any perceived risks associated with the presence of impurities in certain lots.

168. Therefore, contrary to Dr. Conti's assumption that at-issue VCDs are worthless, from the perspective of consumers and other industry participants, including P&T committees and regulatory agencies, proposed class members obtained value from the at-issue VCDs. The efficacy of the drugs allowed proposed TPP and consumer class members to mitigate adverse health outcomes, as well as the associated and higher costs of those outcomes, such as surgeries and emergency room visits, which are more common for patients with uncontrolled hypertension and/or heart failure.[316] Dr. Conti proposes no method or approach to determine the therapeutic value received by proposed class members from purchasing and taking the at-issue VCDs, or any reduction in value associated with the presence of impurities in certain lots.

B. Dr. Conti Fails to Account for the Fact that Proposed Class Members Would Have Incurred Different Offsetting Costs

169. As explained above, proposed consumer class members have an incentive to take maintenance therapies, such as anti-hypertensive drugs, and proposed TPP class members have an incentive to encourage consumers to take these therapies to mitigate adverse health outcomes and higher potential costs. If proposed class members would not have purchased the at-issue VCDs, as Dr. Conti appears to argue in her report, then consumers and TPPs would likely have incurred either (1) costs associated with adverse health outcomes or (2) costs associated with the purchase of alternative therapies, such as the branded versions of VCDs or other treatments of hypertension and heart failure, to mitigate those adverse health outcomes. Dr. Conti does not address these costs.

170. Valsartan is just one of many different drugs indicated to treat hypertension and heart failure. For example, there are many other ARB drugs that have a similar mechanism of action to VCDs. Examples include azilsartan, candesartan, eprosartan,

[316] Cutler, David et al., "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation," *Health Affairs*, Vol. 26, No.1, 2007, pp. 97-110.

irbesartan, losartan, olmesartan, and telmisartan.[317] There are also other classes of hypertension drugs: diuretics, beta-blockers, ACE inhibitors, calcium channel blockers, alpha blockers, alpha-2 receptor agonists, combined alpha and beta-blockers, central agonists, peripheral adrenergic inhibitors, and vasodilators.[318] Each of these drug classes aims to lower blood pressure, although the mechanism of action differs. Many anti-hypertensive combination drugs are also available—for example, drugs that combine two diuretics, an ARB and a diuretic, a beta blocker and a diuretic, or a calcium channel blocker and an ACE inhibitor.[319]

171. Similarly, many of the same drug classes used to treat hypertension, as well as other drug classes, are used to treat heart failure. Drug classes used to treat heart failure include ACE inhibitors, ARBs, angiotensin-receptor neprilysin inhibitors ("ARNIs"), I_f channel blockers, beta blockers, aldosterone antagonists, and diuretics.

172. As discussed in **Section III.C**, P&T committees typically include multiple drugs and drug classes used to treat hypertension and heart failure on formularies to ensure patient access to those therapies, which are considered to be cost-effective, particularly compared to the costs of adverse health outcomes (e.g., stroke or heart attack). For example, in SummaCare's 2012 Medicare Comprehensive Formulary, there were [redacted][320] When considering all alternative treatments for hypertension, this can total well over [redacted] in a single formulary.[321]

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317 Mayo Clinic, "Angiotensin II receptor blockers," August 13, 2021, available at https://www mayoclinic.org/diseases-conditions/high-blood-pressure/in-depth/angiotensin-ii-receptor-blockers/art-20045009.

318 When asked "[d]oes Emblem or ConnectiCare consider ACE inhibitors to be suitable alternative drugs to ARBs?," Ms. Finn confirmed, "Emblem considers both classes of drugs to be suitable. It's up to the physician to determine which is the best for that particular patient. And we will dispense and process what that provider has requested, providing that the member meets the criteria." (Finn Deposition, EmblemHealth and ConnectiCare, July 30, 2021, pp. 149:23-150:6)

319 Skolnik, Neil S. et al., "Combination Antihypertensive Drugs: Recommendations for Use," *American Family Physician*, Vol. 61, No. 10, May 2000, pp. 3049-3056.

320 MSP-SUMMACARE-000162-0274, at 0216.

321 Calculated from MSP-SUMMACARE-000162-0274 using [redacted]

173. From a business perspective, to determine how costs would have been affected if purchases of at-issue VCDs had not occurred, a substantial amount of information would be required. Given the wide variety of potential alternative therapies to valsartan both for hypertension and heart failure, coupled with the range of pharmacy benefit programs offered by TPPs, to determine whether and the extent to which proposed class members would have paid less if they had not purchased at-issue VCDs, one must be able to determine (1) the amounts paid for VCD prescriptions by each party, which as I explained above vary substantially; (2) whether those prescriptions would have been different (i.e., written for a different treatment), which may vary across beneficiaries and their healthcare providers; and (3) whether the prices that *would have been* paid by the various parties to the transaction are lower, higher, or the same as the amount that had been paid for the VCD prescriptions, which vary across pharmacy benefit programs. This is especially challenging to track as many TPPs have formularies that include many of these potential alternative therapies.[322]

174. The use of alternative drugs indicated for hypertension in the absence of the at-issue VCDs is consistent with testimony of economic loss consumer class representatives, which shows that patients who stopped therapy with the at-issue VCDs purchased an alternative therapy. Many of the economic loss consumer class representatives switched to alternative blood pressure medications, and specifically switched to other VCDs, such as olmesartan, irbesartan, or losartan, after the recall.[323] Dr. Conti fails to account for these alternative prescriptions and corresponding costs that would have occurred had consumers and TPPs not paid for the at-issue VCDs.

C. Dr. Conti Inappropriately Ignores the Role of Government Payors

175. Dr. Conti ignores the outsized role of government payors (parties excluded from the proposed classes) in the purchase of prescriptions for treatments of hypertension

322 I understand that the economic implications of the availability of alternative therapies are being discussed by the Defendants' economic expert, Dr. Lauren Stiroh.

323 *See, e.g.,* [redacted]

and heart failure,[324] and proposes no method by which to determine the costs that were borne by proposed TPP and consumer class members, as opposed to the non-class members, such as government payors.

176. As discussed in **Section III.D** and **Section IV.B**, Medicare Part D (PDP and MA-PD) plans are generally considered within the pharmaceutical industry to be government-funded because they receive prospective subsidies from the federal government for their beneficiaries' claims and make payments using those subsidies to cover a portion of their beneficiaries' prescriptions. These direct subsidies, in addition to the reinsurance, from the federal government are expected to cover nearly three-quarters of a plan's total costs across all benefits.[325] Dr. Conti completely ignores the role of the federal government in her proposed damages methodology, which results in an enormous overstatement of potential damages. In fact, [redacted][326]

177. Importantly, in addition to the prospective subsidies that are received by providers of government-funded prescription drug programs (e.g., Medicare Part D Plans), the federal government further mitigates the risk of the cost of prescriptions to those providers.[327] For example, as discussed in **Section III.D**, risk corridors ensure that the federal government pays at least half the amount if plan sponsor's costs are at least 5 percent higher than the bid; the catastrophic phase of the Part D benefit design is a form of reinsurance and additional subsidy. In addition, certain low-income patients receive extra help from the federal government from beneficiary premiums and cost-sharing obligations. The federal government also offers the Employer Retiree Drug Subsidy to other plans that offer prescription drug coverage to people who are eligible for Medicare. Dr. Conti does not account for any of these payments by the federal government, which is excluded from the proposed classes under Plaintiffs' proposed class definitions.

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324 *See, e.g.,* Kirchhoff, Suzanne M., "Medicare Part D Prescription Drug Benefit," Congressional Research Service, December 18, 2020, available at https://sgp fas.org/crs/misc/R40611.pdf, p. 1.

325 MedPac 2017 Report on Medicare Part D, p. 413.

326 Backup production to this report.

327 *See, e.g.,* Kirchhoff, Suzanne M., "Medicare Part D Prescription Drug Benefit," Congressional Research Service, December 18, 2020, available at https://sgp fas.org/ crs/misc/R40611.pdf, p. 1.

D. Dr. Conti Fails to Acknowledge that Some Proposed Class Members Received Reimbursement for the At-Issue Valsartan Products

178. Dr. Conti has also failed to account for proposed class members who were reimbursed for some of their purchases of recalled VCDs. Following the voluntary recalls, some manufacturers and mail-order pharmacies set up channels to allow consumers to return the recalled products and receive a credit or reimbursement. For example, at the manufacturer level, [redacted],[328] [redacted][329]

179. Several pharmacies and TPPs also facilitated returns of affected products. [redacted][330] [redacted].[331] Similarly, representatives from Walgreens, Albertsons, Rite Aid, Humana and Kroger all testified that their pharmacies sent out letters or called patients to inform them about return or replacement instructions for the recalled VCDs.[332] In July 2018, [redacted][333]

180. Dr. Conti's damages calculation does not attempt to quantify or account for reimbursements or credits paid to proposed class members who returned recalled VCDs, which would reduce any alleged economic losses.

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328 [redacted]

329 MSP-SUMMACARE-005888-5912, at 5891.

330 MSP-EMBLEM-000400.

331 MSP-FALLON-005484-5488; CVS Caremark, "Medication Safety Alerts," available at https://www.caremark.com/wps/portal/DRUG_SAFETY_ALERTS_FOR_PATIENTS?cms=CMS-PWCM-1107740.

332 Stimmel Deposition, Walgreens, pp. 43:22-44:3; Shaal Deposition, Albertsons, pp. 159:16-160:11, 190:22-191:6; McMahon Deposition, Rite Aid, pp. 83:8-84:2, 181:20-182:16; Deposition of Cesar Cedeno, Associate Director at Humana, September 27, 2021 ("Cedeno Deposition, Humana"), pp. 71:25-73:17. Turner Deposition, Kroger, p. 165:11-166:13.

333 MSP-FALLON-005644-5646 at 5644.

E. Dr. Conti's Calculation of Unjust Enrichment Fails to Account for the Complex Pharmaceutical Supply Chain and All Costs Incurred by Retail Pharmacy and Wholesaler Defendants, Leading to Inaccurate and Overstated Profits

181. I understand that Plaintiffs do not assert claims on behalf of the TPP class against the Retail Pharmacy Defendants and that Dr. Conti was not asked to calculate proposed TPP class damages for the Retail Pharmacy Defendant-specific theories of liability.[334] Although Dr. Conti has performed a calculation of her proposed methodology for Retail Pharmacy Defendants' unjust enrichment, she has not performed such a calculation for Wholesaler Defendants.[335]

182. In Dr. Conti's proposed methodology to calculate alleged unjust enrichment for Retail Pharmacy Defendants and Wholesaler Defendants, she defines unjust enrichment as revenues minus costs.[336] While I offer no opinion on the legal definition of "unjust enrichment," Dr. Conti's calculations do not accurately reflect a reliable estimate of Retail Pharmacy Defendants' profits, and fail to account for the complexities inherent in the numerous contractual relationships that would inform these Defendants' revenues and costs.

183. As illustrated in **Figure 1** and discussed in **Section III.A**, pharmacies and wholesalers are situated in the middle of the supply chain. Wholesalers purchase drugs from manufacturers and then sell from their inventory to pharmacies. Pharmacies purchase drugs from manufacturers or wholesalers based on negotiated, and frequently changing, contract terms. The pharmacies then store and dispense those drugs to patients. Revenues, costs, and offsets for both Retail Pharmacy Defendants and Wholesaler Defendants would need to be taken into account in any appropriate methodology to determine alleged unjust profits.

1. Dr. Conti's Calculation of Unjust Enrichment for Retail Pharmacy Defendants Does Not Account for All Relevant Costs

184. For the calculation of Retail Pharmacy Defendants' unjust enrichment, Dr. Conti sums consumer paid amounts in the claims data from Retail Pharmacy Defendants. She claims that these amounts already account for dispensing fees, but fails to acknowledge that dispensing fees are not the same as costs, and she does not attempt to account for any

334 Dr. Conti refers to TPPs as end payors. Conti Declaration, at ¶¶ 1, 59.

335 Conti Declaration, at ¶ 86

336 Conti Declaration, at ¶¶ 63-67, 82.

other costs.[337] As a result, her calculation does not remove costs actually incurred by Retail Pharmacy Defendants in procuring medication for and dispensing prescriptions to patients.

185. Specifically, Dr. Conti fails to account for costs associated with purchasing the drugs that are later dispensed to patients, as well as other dispensing costs, which include overhead and labor costs that, based on my experience, are not fully reimbursed by dispensing fees. Dr. Conti also fails to account for any adjustments after the point-of-sale transaction, such as DIR fees. These dispensing costs are estimated to average $12.40 per prescription,[338] which, if included, would significantly reduce her estimate of unjust enrichment. These are all standard costs incurred by pharmacies and accounted for in standard industry profit measures, although they are not typically available on a drug-by-drug basis.[339] Dr. Conti's estimates of unjust enrichment for Retail Pharmacy Defendants are therefore overstated.

186. From a business perspective, it is not clear what Dr. Conti is attempting to calculate by subtracting dispensing fees from copay amounts received by Retail Pharmacy Defendants. The difference in those amounts does not reflect any standard metric of pharmacies' profits, nor does it provide any indication of whether a Retail Pharmacy Defendant earned a profit on the sale of a particular prescription.

187. Different pharmacies have different costs and cost structures. As I explained in **Section III.A**, pharmacies may negotiate the ability to buy products outside of their prime vendor contracts with wholesalers,[340] and pharmacies will ask generic manufacturers to bid

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337 Conti Declaration, at ¶ 78.

338 Shoemaker-Hunt et al., "Cost of Dispensing Study," Abt Associates, January 2020, available at https://www nacds.org/pdfs/pharmacy/2020/NACDS-NASP-NCPA-COD-Report-01-31-2020-Final.pdf, p. iv.

339 *See, e.g.,* CVS Health Corporation, Form 10-K, December 31, 2019, available at http://d18rn0p25nwr6d.cloudfront.net/CIK-0000064803/bda80622-775c-425f-8300-a7b8f84caa0d.pdf, p. 60; Rite Aid Corporation, From 10-K, February 29, 2020, available at https://s27.q4cdn.com/633053956/files/doc_financial/annual/2020/fy20-form-10K.pdf, pp. 85-86; Carroll, Norman V. et al., "Analysis of Costs to Dispense Prescriptions in Independently Owned Long Term Care Pharmacies," National Community Pharmacists Association, February 2013, available at http://www ncpa.co/pdf/ltc/LTC-CTD-Study-Final-Report(1).pdf, p. 25; CMS, "Medicare Part D – Direct and Indirect Remuneration (DIR)," January 19, 2017, available at https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.

340 *See* **Section III.A**. [redacted]

on these products to secure supply.[341] These negotiations typically apply to a select group of generic products.[342] The cost of these products is determined by individually negotiated terms between pharmacies and suppliers, and I am aware of no single source of information that would provide this information regarding all members of the proposed class.

188. Beyond these limitations in calculating standard measures of profit from at-issue VCDs for different pharmacies, pharmacies' profits from the sale of these drugs are likely to be low. Pharmacies generally have low profit margins according to standard metrics of pharmacies' profits. For example, Rite Aid reported that its retail pharmacy segment generated an adjusted EBITDA of 3 percent of revenues in their fiscal 2021 second quarter results.[343] Walgreens reported an operating margin of 2.5 percent for U.S. retail pharmacy operations in its Form-10-Q for the fiscal year ended August 31, 2020.

189. Lastly, Dr. Conti fails to account for any refunds or reimbursements that Retail Pharmacy Defendants received in her calculation of unjust enrichment. [redacted][344] Similarly, Solco's recall also promised a credit memo for returned at-issue products.[345] In fact, [redacted][346] Dr. Conti's methodology is therefore overly simplistic and fails to account for the true costs that Retail Pharmacy Defendants incurred for VCDs.

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341 *See* McMahon Deposition, Rite Aid, pp. 27:16-28:13.

342 *See, e.g.,* Retailer Pharmacy Defendants' Letter, Exhibit I (Declaration of Erin McCoy, Senior Director of Payer Relations at CVS, June 15, 2020) at ¶¶ 6-7.

343 EBITDA refers to earnings before interest, taxes, depreciation, and amortization. Rite Aid, "Rite Aid Corporation Reports Fiscal 2021 Second Quarter Results," September 24, 2020, available at https://investors.riteaid.com/news/news-details/2020/Rite-Aid-Corporation-Reports-Fiscal-2021-Second-Quarter-Results-2020-9-24/default.aspx.

344 MSP-SUMMACARE-005888-5912, at 5892-5893.

345 Prinston Pharmaceutical Inc., dba Solco Healthcare LLC., "Company Announcement," July 16, 2018, available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/prinston-pharmaceutical-inc-issues-voluntary-nationwide-recall-valsartan-and-valsartan-hctz-tablets.

346 Taylor Deposition, OptumRx, pp.167:15-24, 205:2-22. McMahon Deposition, Rite Aid, pp. 130:17-131:1. Cesar Cedeno Deposition, Humana, September 27, 2021, pp. 57:23-58:6.

2. Dr. Conti's Proposed Methodology for Calculating Unjust Enrichment for Wholesaler Defendants Does Not Account for All Relevant Costs

190. While Dr. Conti does not calculate unjust enrichment for Wholesaler Defendants, she proposes a methodology that she states could be used to calculate unjust enrichment for Wholesaler Defendants if "provide[d] with the appropriate input data."[347] However, even determining whether a particular at-issue VCD prescription filled for a consumer or TPP class member was sold through a wholesaler or was directly purchased by the pharmacy from a manufacturer is not possible with prescription-level claims data.

191. As discussed in **Section IV.C**, the lot number and expiration date required to trace a drug dispensed to a proposed class member back through the supply chain to the manufacturer do not exist. Furthermore, to the degree that the price paid by the consumer and the price paid by the TPP needs to be allocated throughout the pharmaceutical supply chain, this allocation would require accounting for the complex set of contracts among (1) TPPs and consumers; (2) TPPs, PBMs, and pharmacies; and (3) pharmacies, wholesalers, and manufacturers. These contractual relationships, as described, in **Section III.A**, are independently negotiated between different sets of entities in the pharmaceutical supply chain, and the specific negotiated terms and prices vary from entity to entity over time. As such, I am aware of no single source of information that would provide this information regarding all members of the proposed class.

192. In addition, Dr. Conti's proposed methodology oversimplifies Wholesaler Defendants' revenues and costs, which are also driven by individualized contracts with upstream manufacturers and downstream pharmacies. For example, [redacted][348][redacted]

347 Conti Declaration, at ¶ 86.

348 For example, [redacted]

[redacted][49]

193. Given this pricing structure, [redacted][350] [redacted][351] [redacted][352] [redacted][353]

194. More broadly, to correctly calculate revenues and costs for Retail Pharmacy Defendants and Wholesaler Defendants, a review of individualized contracts between different parties throughout the pharmaceutical supply chain would be required. As discussed in **Section III**, pharmacies and wholesalers each have separately negotiated agreements with both upstream and downstream entities: pharmacies have contractual relationships with manufacturers, wholesalers, PBMs, and TPPs; wholesalers have contractual relationships with manufacturers and pharmacies but do not contract with PBMs or TPPs and are not directly connected to those transactions. This complex set of individually negotiated terms and agreements result in different acquisition costs and reimbursements for generic medications that Dr. Conti fails to even consider. Dr. Conti's

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349 *See also* Sample Declaration, AmerisourceBergen, at ¶ 16; Declaration of Brian Renner, Director of Finance at Cardinal Health, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, June 16, 2020 ("Renner Declaration, Cardinal Health"), at ¶ 8.

350 Renner Declaration, Cardinal Health, ¶ 12.

351 Renner Declaration, Cardinal Health, ¶¶ 2, 8, 12.

352 Renner Declaration, Cardinal Health, ¶ 10.

353 Renner Declaration, Cardinal Health, ¶ 12.

failure to account for these contracts and market complexities therefore results in inaccurate estimates of industry profits, leading to overstated damages.

VI. Dr. Panagos' Characterization of Reliance on the FDA's Orange Book Does Not Align with Industry Practice

195. Dr. Panagos was retained by Plaintiffs' counsel "to render an opinion regarding what information third party payors […] rely on and consider with respect to generic drugs and, more specifically, the Valsartan and Valsartan Containing Drugs at issue in this litigation."[354] She opines that [t]he 'AB' rating in the FDA Orange Book, based as it is on the generic drug manufacturer's ANDA, represents a manufacturer's warranty to TPPs and P&T Committees for placement on a prescription drug formulary."[355] Dr. Panagos' assertion is inaccurate and misleading. Based on my experience in the industry, TPPs do not rely on the Orange Book for decisions to reimburse members' claims. P&T committees merely use the Orange Book to determine the equivalence rating for generic drugs. It has been my experience with P&T committees that they maintain a listing of generic products that are losing patent protection in the next two to three years and an estimated date for market entry. Once a generic enters the market and there is sufficient supply of the product, the P&T committee may review and add the product to their formularies or establish a policy to automatically add newly approved generics.

196. A P&T committee is unlikely to view a listing in the Orange Book as a manufacturer's warranty. A review of the 41st edition of the Orange Book, reveals there is no mention of a warranty. Dr. Panagos provides no evidence that P&T committees rely on the Orange Book as a "warranty" from manufacturers, and based upon my personal experience serving on various P&T committees, they do not consider the Orange Book to represent any sort of warranty. Dr. Panagos, who does not refer to any personal P&T Committee experience, provides no evidence, source, or industry standard that P&T committees rely on the Orange Book as a "warranty" from manufacturers.

354 Panagos Declaration, at ¶ 1.

355 Panagos Declaration, at ¶ 47.

A. Purpose of the FDA's Orange Book and Use in the Industry

197. The Orange Book was developed to provide a "list of all prescription drug products that are approved by FDA for safety and effectiveness, along with therapeutic equivalence determinations for multisource prescription products."[356] For several decades, states have encouraged the substitution of drug products through laws and regulations in attempt to lower drug costs. In response, the FDA created the Orange Book to serve as a guide for generic substitution among drugs, based on common criteria.[357] Editions of the Orange Book are released annually, along with monthly Cumulative Supplements.[358]

198. The Orange Book is used by PBMs through their P&T committees to assess drugs and their attributes as part of formulary design. As I explained in **Section III.C**, PBMs rely on P&T committees to manage their formularies. These P&T committees use the Orange Book only to evaluate whether generic versions of drugs (as a whole) are available to be included on the formulary; P&T committees do not consider generic medications from individual manufacturers in their decision-making. Any consideration of generic medications from individual manufacturers is an operational decision (i.e., when to establish a MAC price), typically made by the pharmacy network administration department, and not within the scope of the P&T committee.

199. P&T committees rely on a wide range of documents and sources to develop formularies. For example, the Academy of Managed Care Pharmacy ("AMCP") recommends that P&T committees "review and evaluate the medical and clinical evidence from the literature, relevant patient utilization and experience, economic data, and provider recommendations."[359] P&T committees also rely on FDA-approved package inserts, the

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356 FDA, "Orange Book Preface," January 21, 2021, available at https://www fda.gov/drugs/development-approval-process-drugs/orange-book-preface.

357 FDA, "Approved Drug Products with Therapeutic Equivalence Evaluations," 2021, available at https://www fda.gov/media/71474/download, p. iv. *See also*, FDA, "From Our Perspective: The Orange Book at 40: A valued FDA Resource Continually Enhanced by User Input," October 26, 2020, available at https://www fda.gov/drugs/news-events-human-drugs/our-perspective-orange-book-40-valued-fda-resource-continually-enhanced-user-input.

358 FDA, "Approved Drug Products with Therapeutic Equivalence Evaluations," 2021, available at https://www fda.gov/media/71474/download, p. xxv.

359 AMCP, "Formularies," June 24, 2019, available at https://www.amcp.org/policy-advocacy/policy-advocacy-focus-areas/where-we-stand-position-statements/formularies.

product label, published data from clinical trials, and relevant patient experiences.[360] In my experience, P&T committees also rely on information in the AMCP dossier, in terms of how the product should be used and its place in therapy. Members of the P&T committee rely on these documents and sources to "provide their insight into the quality of the published literature, share their clinical practice experience, and assess the relative place in therapy of the medication and therapy class."[361] P&T committees also meet regularly to re-evaluate and update formularies to "reflect the best medical practices and new clinical and economic evidence."[362]

200. In contrast to PBMs, in my experience, TPPs typically do not use the Orange Book. As discussed in **Section III.C**, TPPs are instead given the option to review and either adopt a formulary "as-is" or customize the PBM formulary. Some TPPs that are health insurers, [redacted] have their own P&T committees that may conduct a review of medications independent of the PBM's P&T committee;[363] however, they will typically follow the process outlined above and similarly not rely on the Orange Book. Based on my experience with self-funded employers, there is rarely, if ever, direct review of the Orange Book.

B. Dr. Panagos Mischaracterizes P&T Committees' Use of the Orange Book

201. Dr. Panagos correctly states in her report that the Orange Book "contains a list of all the drugs approved for marketing in the United States" and is used "as guidance in creating formularies and to regulate substitution."[364] However, Dr. Panagos asserts, but provides no support, that P&T committees use the Orange Book as a "warranty" for generic medications.[365] She claims that the therapeutic equivalence ratings in the Orange Book

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360 Express Scripts, "White Paper: Formulary Development at Express Scripts," December 2020, available at https://express-scripts.com/aboutus/formularyinformation/development/formularyDevelopment.pdf; AMCP, "Principles of a Sound Drug Formulary System," October 2020, available at https://www.amcp.org/sites/default/files/2019-03/Principles%20of%20a%20Sound%20Drug%20Formulary%20System.pdf.

361 Express Scripts, "White Paper: Formulary Development at Express Scripts," December 2020, available at https://express-scripts.com/aboutus/formularyinformation/development/formularyDevelopment.pdf.

362 AMCP, "Formularies," June 24, 2019, available at https://www.amcp.org/policy-advocacy/policy-advocacy-focus-areas/where-we-stand-position-statements/formularies.

363 [redacted]

364 Panagos Declaration, ¶ 29.

365 Panagos Declaration, ¶¶ 47, 56-57.

"[represent] a manufacturer's warranty to TPPs and P&T Committees for placement on a prescription drug formulary."[366]

202. Dr. Panagos' assertion of a "warranty" from the Orange Book is not supported by the purpose and/or intent of the Orange Book. The Orange Book provides information about drugs approved by the FDA, but it does not provide information regarding recalls or imply that products have not been recalled. In fact, the introduction of the Orange Book states that "[i]nclusion of products in the Orange Book is independent of any current regulatory action being taken administratively or judicially against a drug product" and that any removal of the product from the market through recall, seizure, or other enforcement is "independent of the inclusion of a product in the Orange Book."[367]

203. Dr. Panagos' conclusion that the Orange Book "serves as the warranty for the medication ensuring that it meets the quality standards outlined by FDA" is inaccurate and mischaracterizes the purpose of the Orange Book and how it is used in standard industry practice.

Signed on the 12th day of January, 2022.

Timothy E. Kosty, R.Ph.

366 Panagos Declaration, ¶ 47.

367 FDA, "Approved Drug Products with Therapeutic Equivalence Evaluations," 2021, available at https://www fda.gov/media/71474/download, pp. iv, xii ("From time to time, approved products may be found in violation of one or more provisions of the FD&C Act. In such circumstances, the Agency may commence appropriate enforcement action to correct the violation, if necessary, by securing removal of the product from the market by voluntary recall, seizure, or other enforcement actions. Such regulatory actions are, however, independent of the inclusion of a product in the Orange Book. The main criterion for inclusion of a product is that it has an NDA or ANDA that has been approved and that has not been withdrawn for safety or efficacy reasons.").

APPENDIX A

Curriculum Vitae

Pharmacy Healthcare Solutions, Inc.

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QUALIFICATIONS

Mr. Kosty has over thirty-eight years of pharmacy experience, predominantly in the upper level management of pharmacy chains and pharmacy benefit managers. Mr. Kosty's recent projects have involved pharmaceutical manufacturers, pharmacy benefit managers, HMOs, software companies, retail pharmacy, long term care organizations, and Medicaid fiscal intermediaries. Mr. Kosty specializes in information technology, claims processing systems, third party management and financial analysis, client and pharmacy network contracting, rebate contracting, client eligibility and reporting, and plan start-up and implementation.

WORK HISTORY

1996- current *President, Pharmacy Healthcare Solutions, Inc.*

Responsible for the overall performance of Pharmacy Healthcare Solutions, Inc., primarily focused on business development and strategic consulting projects with virtually all segments of the pharmacy industry.

2018-current *Co-Founder, Pharmacy Healthcare Solutions, LLC.*

Responsible for transitioning managerial responsibility to new owners while mentoring new ownership on consulting strategies, tactics, and operational efficiencies.

1992-1996 *Manager, Third Party Operations*

Manager, Managed Care Operations and Product Development

Thrift Drug, Inc.

TDI Managed Care Services, Inc.

Built and managed an administrative organization to support PBM product sales and service. Created and negotiated nationwide network of retail pharmacies with appropriate contracts, administrative functions, and controls. Created a customer service function to respond to client, member, and pharmacy telephone inquiries. Led the functional evaluation, selection and installation of a multi-million dollar claims processing system to handle on-line real-time claims adjudication. Responsible for information systems development projects to enhance product offering.

1986-1992 *Manager, Third Party Operations, Rite Aid Corporation*

Supervised six departments including information center, reject processing, claims processing, insurance carrier adjustments, drug file and enrollments. Developed store systems for processing on an IBM mainframe; involved the design, testing, and implementation of claims and rejection systems. Installed automated reject correction system that decreased turn-around time from ninety to three days; integrated more than 200 pharmacy chain acquisitions into third party operations including the transition process to convert acquired store systems; coordinated the collection of outstanding receivables for the acquired companies.

1984-1986 *Pharmacy Supervisor, Southern West Virginia, Rite Aid Corporation*

Responsible for the management and staffing of twenty-five pharmacies in Southern West Virginia and South-Western Virginia District, which, during this tenure, was the most profitable in the Company with three of the top ten pharmacies in terms of prescription volume and profits in the company.

1983-1984 *Pharmacy Manager, Whitesville, West Virginia, Rite Aid Corporation*

EDUCATION

1993 Masters of Business Administration, Pennsylvania State University

1983 Bachelor of Science, Pharmacy, The Ohio State University

Memberships in Professional Organizations

Academy of Managed Care Pharmacy (AMCP)

American Society Automation in Pharmacy (ASAP)

American Pharmaceutical Association (APhA)

National Association of Chain Drug Stores (NACDS)

National Council for Prescription Drug Programs (NCPDP)

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Kosty, T.E., Johnson, A.E., "Prognostications for 2022", *ComputerTalk for the Pharmacists, November/December 2021.*

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Kosty, T.E., Dietz, D.J., "Training Support with a New Technology Solution?" *Computer Talk for the Pharmacists,* November/December 2017

Kosty, T.E., Johnson, A.E., "Amazon: Pharmacy Disrupter or Tough Going?" *Computer Talk for the Pharmacists,* September/October 2017

Kosty, T.E., "Drug Utilization Alerts: Failures and Future Direction" *Computer Talk for the Pharmacists,* July/August 2017

Kosty, T.E., Dietz, D.J., "The Outlook for 2017" *Computer Talk for the Pharmacists,* January/February 2017

Kosty, T.E., Dietz, D.J., "Performance Networks" *Computer Talk for the Pharmacists,* September/October 2016

Kosty, T.E., "Final AMP Rule: Industry Implications" *Computer Talk for the Pharmacists,* July/August 2016

Kosty, T.E., Dietz, D.J., "The Market Impact of Pharmacy Consolidation" *Computer Talk for the Pharmacists,* January/February 2016

Kosty, T.E., Dietz, D.J., "OIG Concerns with Co-pay Discount Programs" *Computer Talk for the Pharmacists,* November/December 2014

Case 1:19-md-02875-RMB-SAK Document 2040-6 Filed 05/03/22 Page 11 of 12 PageID: 63746

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Kosty, Tim E., "AMP Reimbursement Update and Future Considerations" Presented at ASAP 2011 Annual Industry & Technology Issues Conference, Amelia Island, FL January 20-22, 2011

Kosty, Tim E., "AWP Settlement Update: Market Impact and Unintended consequences" Presented at ASAP 2010 Annual Industry & Technology Issues Conference, The Sanctuary, Kiawah Island, SC January 14-16, 2010

APPENDIX B
EXPERT TESTIMONY IN THE PAST FOUR YEARS

1. *Painters and Allied Trades v. Takeda Pharm.*
   Case No. 2:17-cv-07223-JWH (AS)
   United States District Court for the Central District of California
   Submitted expert report.

2. Confidential Arbitration Related to Pharmacy Claims
   Submitted expert report.

3. *The Great Atlantic & Pacific Tea Company, Inc., v. McKesson Corporation*
   Case No. 7:15-bk-23007-RDD
   United States Bankruptcy Court for the Southern District of New York
   Submitted expert report and provided deposition testimony.

4. *In Re Loestrin 24 FE Antitrust Litigation*
   MDL No. 1:13-md-2472-WES-PAS
   United States District Court for the District of Rhode Island
   Submitted expert report and provided deposition testimony.

APPENDIX C
MATERIALS RELIED UPON

Court Documents

Filings

Defendant CVS Pharmacy Inc.'s Response to Plaintiffs' Second Amended Sets of Requests for Production of Documents to Retail Pharmacy Defendants, *In Re: Valsartan Products Liability Litigation*, MDL No. 2875, United States District Court, District of New Jersey, August 14, 2020.

Memorandum of Law in Support of the Medical Monitoring Plaintiffs' Motion for Class Certification, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021.

Plaintiffs' Memorandum of Law in Support of their Motion for Class Certification of Consumer Economic Loss Claims, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021.

Plaintiffs' Motion for Class Certification of Consumer, Third Party Payor, and Medical Monitoring Claims, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021.

Retailer Pharmacy Defendants' Letter Re: Macro Discovery Disputes, *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, Case No. 1:19-md-02875-RBK-JS, June 16, 2020.

Third Amended Consolidated Economic Loss Class Action Complaint, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 1, 2021.

Third Party Payors' Brief in Support of Motion to Certify Class, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021.

Depositions

Defendant Fact Witnesses

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[redacted]

Consumer and TPP Class Representatives and Related Entities

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Defendant Scientific Experts

Deposition of Michael Bottorff, Professor and Department Head of Pharmacy Practice at Manchester University, September 16, 2021.

Plaintiff Expert Declarations (Including All Produced Data Sources and Documents Relied Upon)

Expert Report of Kali Panagos, Pharm.D., R.Ph., *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021.

Expert Declaration of Laura R. Craft, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021.

Expert Declaration of Rena Conti, Ph.D., *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, United States District Court, District of New Jersey, November 10, 2021.

Materials in Plaintiffs' Experts' Backup Production Cited in this Report

Third-party data

IQVIA Xponent data, including data dictionaries

Retail Pharmacy Defendant data

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